

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

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

Out of 26 consecutive patients treated with OTSC in this study, 10 patients suffered from acute and 16 patients from chronic leaks (fistulas). The mean defect diameter was 8.7 mm. 14 cases were complicated by recto-vaginal, rectovesical or colo-cutaneous fistula. In 3 cases OTSC was used to complete endoscopic vacuum-assisted closure of large defects.

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

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

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

Bonino MA, Verra M, Salvai A, Bullano A, Rapetti L, Arezzo A and Morino M (2014)

20th National Congress of Digestive Diseases, Napoli, Italy, March 19-22 2014

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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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, gastrogastic, 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.

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OTSC® update 20

August 2015 | Clinical experience with OTSC shows high success rate for recurrent bleeding and complex resections

E. Wedi and J. Hochberger of the Department of Hepato-Gastroenterology at the University Hospital of Strasbourg, France, reported on clinical experiences with the over-the-scope clip system and its application aids such as the OTSC Twin Grasper and OTSC anchor for coarse tissue.

They present a review of 14 clinical studies on OTSC use and add their own experiences with 84 patients (101 OTSC applications). All Strasbourg patients suffered from recurrent bleeding/lesions of perforations and fistulae or post-operative leakage. 78 out of 84 cases (92.85%) could be treated successfully.

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

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

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

The paper concludes that OTSC is an asset in interventional endoscopy, especially in case of complex endoluminal resections. According to the literature, OTSC is especially useful for closure of perforations of up to 1.3 cm (and much larger in individual cases) and bleeding lesions with a high risk of recessive bleeding, e.g. in anti-coagulated patients or treatment of acute Forrest Ia/b hemorrhage.

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

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

Wedi E, Hochberger J (2014)

Endo-Praxis, 30.1, 14-17

dx.doi.org/10.1055/s-0034-1370894

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

A team from Kagawa University, Japan, around Dr. S.

Fujihara, Department of Gastroenterology and Neurology, together with Dr. Kazi Rafiq, Department of Pharmacology, conducted a study exploring prophylactic closure after colorectal endoscopic submucosal dissection (ESD) using the OTSC clip as a preventative measure.

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

The study included 68 patients (39 male, 29 female) whose colorectal tumors (mean tumor size 35.4 mm) were treated with ESD. Prophylactic closure was performed on patients with excessive coagulation in the muscularis propria or larger resection size (n=27). Closure was performed either with conventional clips (n=18) or OTSC (n=9). OTSC was used for large mucosal defects (>30 mm), in case of flexure of the colon, excessive coagulation in the muscularis propria and when closure could not be achieved with conventional clips. OTSC closure required more time than conventional closure since in 5 cases tumors were located at a sharp bend in the sigmoid colon and required the use of the Twin Grasper. The median of clips needed was 8 for conventional clips (range 4–12) and 1 (range 1–3) for OTSC.

The study showed the efficacy of endoscopic closure after ESD in preventing local peritoneal inflammation and abdominal symptoms without any adverse effects. It did, however, not demonstrate a reduction of perforation and post-operative bleeding. The authors point out the limited sample size of their study and lack of randomization. They call for more randomized prospective studies with more patients to confirm their encouraging results.

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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May 2015 | Conference Report: German Society for Endoscopy and Imaging Procedures (DGE-BV)

The conference, held from March 26–28, 2015 in Munich, featured papers on fistula closure and perforation management (even after EVT or stent therapy) with OTSC, full-thickness resection with FTRD at success rates of well over 80%, treatment of therapy-resistant complicated fistulae with OTSC Proctology, and one presentation on the new remOVE System for OTSC clip removal (currently in development).

Conference Report | talks, posters and videos

45th Conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV)
Munich, Germany, March 26 – 28, 2015

45. DGE-BV-Kongress, München, 26. – 28. März 2015
Deutschen Gesellschaft für Endoskopie und Bildgebende Verfahren e.V.

Chairman: Prof. Dr. Hans-Dieter Allescher,
Garmisch-Partenkirchen

Ovesco products were presented in four workshops on two different topics (hemostasis techniques, held by E. Wedi and A. Nägel respectively, and management of complications led by T. Lankisch and J. Bernhardt respectively). Additionally, several talks, posters and videos discussed products by Ovesco.

OTSC System

Improved fistula closure with OTSC: treatment of fistulae with highly fibrotic openings

A Meining, University Hospital Ulm, together with M.

Bajbouj, Technical University Munich, well as H. Feußner und D. Wilhelm, Technical University Munich, presented a video of a 41-year-old female patient who had developed a large fistula into the bronchial system after resection of the esophagus with gastric interposition due to lye ingestion. Because of coarse, scarred mucosa at the fistula opening in the gastro-esophageal junction it was impossible to permanently and securely anchor an endoscopic clip. Overstenting treatment was also unsuccessful, and the patient had to be tube fed for several weeks.

In order to ensure secure anchoring of the OTSC clip, the mucosa around the fistula opening was incised in a diameter of about 15 mm (corresponding to the opening of the OTSC applicator) with an HF knife. In the uncovered submucosa, the clip could be securely fastened and applied around the fistula with the mobilized mucosal edges covering the opening of the fistula. Administration of a contrast agent confirmed fistula closure, the patient suffered no more aspirations, and endoscopic follow-up after three months confirmed treatment success.

The group recommends incision of the mucosa before application of the OTSC clip in case of coarse and chronically indurated mucosa tissue in order to improve clip anchoring.
Erfolgreicher Verschluss einer großen ösophago-bronchialen Fistel durch mukosale Inzision vor OTSC-Klipp-Platzierung

A. Meining, Ulm; M. Bajbouj, H. Feußner, D. Wilhelm, München

OTSC as treatment option for fistulae, even after EVT or stent therapy

M. Laukötter, T. Vowinkel, D. Palmes, N. Senninger und R. Mennigen, University Hospital Münster, presented two cases in which patients suffered from leaking anastomoses after sleeve gastrectomy.

In the first case, three separate insufficiencies with abscess formation manifested along the staple line in a 50-year-old male. He was treated with endoscopic vacuum therapy (EVT) and a total of 25 polyurethane sponges. The group contrasted this with the case of a 45-year-old woman, who had been unsuccessfully treated with stents after an anastomosis fistula. After the stent had been extracted, one OTSC clip was applied. Treatment duration was eight days. In both cases, no complications occurred during or after and treatment was successful.

The group recommends the OTSC system for fistulae in fresh lesions free from inflammation as well as for rescue treatment after EVT or stent therapy failed.

Endoskopisches Komplikationsmanagement nach Sleeve-Magen-Resektion.

M. Laukötter, T. Vowinkel, D. Palmes, N. Senninger und R. Mennigen, Münster.

OTSC as important treatment option for management of perforations

A. Meining, University Hospital Ulm, emphasized the important role of timing (acute or chronic), pathogenesis and etiology, size and location of a perforation for treatment. He favors the OTSC clip as the best treatment option for perforations during ESD since it is easy to place and offers a higher success rate than other, smaller clips. All in all, he sees OTSC as a useful therapy tool, even for late complications (e.g. after unsuccessful stent placement) and for fistula closure.

Rationales Handeln nach Perforation: Clippen, Stenten oder Sponge?

A. Meining, Ulm.

“Live Demonstration on Stage” on correcting OTSC clip placement

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

OTSC-Clip/Clip Fehlplatzierung.

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

FTRD (Full-Thickness Resection Device)

FTRD for endoscopic full-thickness resection in case of NET

P. Klare, B. Neu, M. Bajbouj, R.M. Schmid und S. von Delius, TU Munich, together with R. Burlefinger, Maria Theresia Hospital, Munich, and K. Specht, TU Munich,

presented a video the treatment of a 50-year-old male with a neuroendocrine tumor (NET). During a screening procedure, the asymptomatic patient had a rectal polyp removed with a snare. Histological examination identified a NET with a proliferation rate < 2 percent, resection was deemed incomplete, a rectal endosonography and PET-CT revealed no pathologic findings.

Six weeks later, an endoscopy revealed a scar at the resection site, and it was decided to perform an endoscopic full-thickness resection using the FTRD System. The edges of the target area were marked and the tissue was pulled completely into the 23 mm long FTRD cap with the FTRD grasper. Then the FTRD Clip was deployed and full-thickness resection was performed using the integrated HF snare. No complications occurred during the procedure and the patient was fit to leave the hospital the next day.

The group stated that NET < 1 cm in size with a low or moderate proliferation rate (G1 and G2) may be resected endoscopically, but that complete resection is a prerequisite for successful treatment. In case of incomplete resection, they deem endoscopic full-thickness resection a minimally invasive treatment option, which enables definitive histological examination.

Endoskopische Vollwandresektion nach R1-Resektion eines neuroendokrinen Tumors im Rektum unter Verwendung eines neuen Over-the-scope Device.

P. Klare, R. Burlefinger, B. Neu, M. Bajbouj, K. Specht, RM Schmid und S. von Delius, München.

Experiences and Recommendations regarding full-thickness resection using the FTRD System

In his presentation, K. Caca, Ludwigsburg hospital, presented clinical data from Ludwigsburg and Zurich of 38 patients treated using FTRD.

In 36 patients, the target lesion could be reached with the FTRD, in 31 of these cases, treatment was technically successful. Average size of the resected tissue was 23.6 mm (12–40 mm) and histological examination confirmed full resection (R0) in 80.5% of cases and full-thickness resection 86.1% of cases. Average duration of hospital stay was 4 days (1–12).

Caca recommends identifying and marking the target lesion without mounted FTRD, marking the lesion with a clip next to the lesion site if necessary, and then rinsing before using the FTRD system. If finding the lesion proves difficult, he recommends fluoroscopy using a TTS balloon (15–20 mm) if appropriate, verifying air insufflation, repeatedly pulling back the endoscope and repositioning the patient. After the resection is performed, the endoscope should be reintroduced without mounted attachment to inspect the resection site. Routine second-look endoscopy the next day is unnecessary if not contraindicated. After 8 to 12 weeks, however, another endoscopy, possibly including clip removal, is advised, although the clip is fully biocompatible and, based on experience, 2/3 of all clips will already have fallen off by then.

Limitations to the procedure are a maximum lesion size of 2.5–3 cm (although the largest lesion treated in this trial was 4 cm) and impaired vision because of the size of the cap. Since the rectum is closely attached to the para rectal tissue in the small pelvis, the procedure often results in “deep resection” rather than full-thickness resection. Caca assesses the FTRD system as valuable and currently the only instrument for full-thickness resection in the lower gastrointestinal tract. He sees FTRD as an effective therapy option for the main indication of non-lifting neoplasia regarding both diag-nosis and treatment.

Endoskopische Vollwandresektion im Kolon mit FTRD.

K. Caca, Ludwigsburg.

„Live Demonstration on Stage“ on FTRD usage

Conference chairman H.-D. Allescher, Garmisch-Partenkirchen hospital, presented the use of FTRD for full-thickness resection on a porcine gastric model in a special 3D demonstration.

3D Bildgebung im klinischen Einsatz. Live-Demonstration on Stage. Sonographie, Laparoskopie und Endoskopie.

Vorsitz: H.-D. Allescher, Garmisch-Partenkirchen. F. Hagemüller, Hamburg. U. Beilenhoff, Ulm, H. Feußner, München und A. Melzer, Dundee/Schottland.

OTSC Proctology

OTSC Proctology deemed effective for closure of

therapy-resistant complicated anal fistulae

R. Mennigen, University Hospital Münster, presented his center's experience in using OTSC Proctology. Technical success rate for fistula closure with OTSC Proctology was 100 percent in 10 patients (5 male, 5 female) with a median age of 41 years (26 to 69). All patients had been treated unsuccessfully before (e.g. mucosa flap, Anal Fistula Plug), and some had undergone several unsuccessful procedures. 4 patients suffered from cryptoglandular fistulae, and in 6 patients fistulae were associated with Crohn's disease.

In 70 percent of patients permanently successful closure and healing was achieved. In 3 patients fistulae recurred (2 cryptoglandular, one patient with Crohn's disease), and the clip dislodged spontaneously after over three weeks. In 3 patients the clip was surgically removed after successful healing of the fistula. Dr. Mennigen deemed the OTSC Proctology system a safe and effective treatment option, even for recurrent complicated anal fistulae.

Verschluss von komplizierten therapierefraktären Analfisteln mit dem OTSC Proctology System.

R. Mennigen, M. Laukötter, T. Vowinkel, N. Senninger und E. Rijcken, Münster.

remOVE (System for OTSC clip removal, in development)**remOVE prototype for treatment of severe dysphagia due to magnetic implant**

A new, promising treatment approach for reflux disease is to augment the lower esophageal sphincter with a magnetic system (LINX® Reflux Management System) consisting of a band of interlinked magnetic beads implanted laparoscopically. A video was presented by M. Bauer, M. Kranzfelder, D. Wilhelm, R. Schirren, A. Jell, H. Friess and H. Feußner, TU Munich, together with A. Meining, University Hospital Ulm.

The video showed a patient suffering from esophageal erosion and resulting dysphagia caused by the LINX® system.

Since there were no other therapy options available, the team was able to treat the patient with the Ovesco clip cutter (trade name remOVE system, market launch planned for 2015), which is not yet available for routine treatment, within "compassionate use". They were able to perform a full endo- scopie removal, leading to complete remission of symptoms.

Perforation eines magnetischen Antirefluxsystems nach intraösophageal-Ösophaguserosion durch ein LINX® system.

M. Bauer, M. Kranzfelder, D. Wilhelm, R. Schirren, A. Jell, H. Friess, H. Feußner, München und A. Meining, Ulm.

May 2015 | OTSC Proctology evaluated favorably at two medical conferences in March 2015

Clinicians presented new data on fistula closure with the OTSC Proctology at the 41st Conference of Coloproctologists as well as at the 45th Conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV), both held in Munich, Germany:

OTSC Proctology proves to be effective, especially in initial intervention

Dr. Lothar Duschka, department of surgery/coloproctology at DKD Helios hospital Wiesbaden, Germany, presented his experience in treating 44 patients using OTSC Proctology. Patient median age was 47 years (24 to 72) with 14 female and 30 male patients. Operating times were between 16 and 95 minutes. Apart from 25 trans-sphincter fistulae, inter-sphincter (3), supra-sphincter (2), recto-vaginal (4) and anal fistulae (8) were included as well as one recto-vesical and one pouch fistula.

During initial intervention, successful closure was achieved in 78 percent of cases. With recurrent fistulae, the success rate was 42 percent. In patients with chronic inflammatory bowel diseases, 64 percent of fistulae were closed successfully. Dr. Duschka praised minimal preparation time at the site of the fistulae when using OTSC Proctology as well as the fact that special variants could often be treated successfully (e.g. 50 percent of recto-vaginal fistulae and the one pouch fistula). He also emphasized a

positive learning curve for the procedure, increasing success rates over time.

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

Al-Haidary J, Zieker D, Borschitz T, Rimpel J, Duschka L Wiesbaden (41. Koloproktologen-Kongress)

OTSC Proctology deemed effective for closure of the therapy-resistant complicated anal fistulae

Dr. Mennigen, department of general and visceral surgery, university hospital Münster, Germany, presented his center's experience in using OTSC Proctology. Technical success rate for fistula closure with OTSC Proctology was 100 percent in 10 patients (5 male, 5 female) with a median age of 41 years (26 to 69). All patients had been treated unsuccessfully before (e.g. mucosa flap, Anal Fistula Plug), and some had undergone several unsuccessful procedures. 4 patients suffered from cryptoglandular fistulae, and in 6 patients fistulae were associated with Crohn's disease.

In 70 percent of patients permanently successful closure and healing was achieved. In 3 patients fistulae recurred (2 cryptoglandular, one patient with Crohn's disease), and the clip dislodged spontaneously after over three weeks. In 3 patients the clip was surgically removed after successful healing of the fistula. Dr. Mennigen deemed the OTSC Proctology system a safe and effective treatment option, even for recurrent complicated anal fistulae.

Verschluss von komplizierten therapierefraktären Analfisteln mit dem OTSC Proctology System

Mennigen R, Laukötter M, Vowinkel T, Senninger N, Rijcken E Münster. (45. DGE-BV-Kongress)

April 2015 | Study identifies OTSC as effective and safe endoscopic therapy for acute gastrointestinal bleeding

In an observational retrospective case series, Dr. Matthew Skinner, Dr. Juan P. Gutierrez, Dr. Helmut Neumann, Dr. C. Mel Wilcox, Dr. Chad Burski and Dr. Klaus Mönkemüller of the Basil I. Hirschowitz Endoscopic Center of Excellence, Department of Gastroenterology, University of Alabama, Birmingham, USA, evaluated the efficacy and safety of OTSC clip placement in patients with upper gastrointestinal bleeding after traditional endoscopic methods had failed.

The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic therapy. Patients had a mean ASA score of 3 (range: 2–4), mean hemoglobin of 7.2 g/dL (range: 5.2–9.1), and shock was present in 75% of patients. They had all received packed red blood cells (mean 5.1 units, range 2–12). Bleeding was due to duodenal ulcer (6), gastric ulcer (2), Dieulafoy lesion (2), anastomotic ulceration (1) and Mallory-Weiss tear (1). Hemostasis was achieved in all patients, but rebleeding occurred in two patients 1 day and 7 days* after OTSC placement. There were no complications associated with OTSC application.

The OTSC System was loaded onto a standard gastro-scope and introduced into the upper gastrointestinal tract under standard direct visualization. The bleeding lesion was located and the gastroscope was maneuvered towards it. Once the OTSC cap was positioned on top of the lesion, full suction was applied to tissue, so that the lesion was fully engulfed inside the transparent cap before the clip was released. In two patients with post-bulbar ulcers, a wire or a wire placed inside a feeding tube was advanced into the distal duodenum and the scope advanced alongside the wire. This measure helped to prevent small-bowel luminal occlusion, which has previously been reported as a major adverse event.

The authors conclude that the OTSC System provides tissue apposition far superior to traditional clipping and can function as a "rescue therapy" in patients with severe non-variceal upper gastrointestinal bleeding in whom prior endoscopic therapies have failed, avoiding more invasive procedures such as embolization or surgery. They point out that the OTSC System appears promising for the treatment of bleeding lesions with large-diameter visible

vessels or those located in awkward positions, such as the greater curvature of the stomach or the posterior duodenal wall, which may not always be amenable to treatment with standard endo- scopes and endoscopic devices.

* Any bleeding occurring more than 72 hours after therapy is usually regarded as a new incident.

Over-the-scope clip placement is effective rescue therapy for severe acute upper gastrointestinal bleeding

Skinner M, Gutierrez JP, Neumann H, Wilcox C, Burski C, Mönkemüller K

Endoscopy International Open 2014; 02: E37–E40 171

March 2015 | JFHOD Congress, France: OTSC in hemostasis – high success rate in anti-coagulated patients

Paris, March 19–22: The JFHOD congress – Journées Francophones d'Hépatogastroentérologie et d'Oncologie Digestive 2015 – the major French clinical congress on gastroenterology, hepatology and GI oncology was held under the presidency of Prof. Jean-Christophe SAURIN.

The group around Prof. J. Hochberger presented their data on OTSC in the treatment of severe gastrointestinal hemorrhage.

Dr. E. Wedi, Dept. Of Gastroenterology and Digestive Endoscopy, University Hospital, Strasbourg, France summarized cases admitted to emergency care due to severe GI bleeding. All patients had Hb <7g/dl upon admission. Median age 73 yrs (29–97). 80% were under concomitant anti-coagulation or antiplatelet therapy. In 87.2% (48/55) bleeding was from a gastroduodenal peptic ulcer, and the remaining from various other causes.

OTSC clips were placed. The overall clinical success rate without recurrence was 83.6% (46/55). In 32.7% OTSC was placed as a salvage treatment due to prior ineffectiveness of other techniques. 12.7% (n=7) had to undergo surgical treatment. Out of these 7 patients 4 died, giving a total mortality rate of 7.2% in this highly challenging case series.

The report by Wedi et al. underlines that patients with a high Rockall score can profit from OTSC treatment, especially patients with anticoagulative or antiplatelet therapy.

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

Munich, March 12–14, 2015:

The annual congress of the German Society for Coloproctology took place in Munich under the presidency of Prof. Dr. h. c. W. Hohenberger, Erlangen.

Dr. L. Duschka and colleagues from the department of colorectal surgery and proctology, DKD Helios hospital, Wiesbaden reported in a plenary lecture about their clinical experience in using OTSC Proctology.

In their abstract (Coloproctology (2015); 1:76) they summarize the data of 22 patients, treated between March and August 2014. The majority had trans-sphincteric fistulas (n=18), followed by inter-sphincteric, rectal, recto-vaginal and pouch fistula (one case each). 13 patients had prior fistula surgery and 8 patients suffered from IBD. Post-surgical follow-up was 3–9 months.

68% of the patients had healing of their fistula, 32% had recurrence. The authors found that patients without prior history of fistula surgery had a higher probability for healing. They conclude that selection of patients is important to optimize the clinical result.

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

Al-Haidary J, Zieker D, Borschitz T, Rimpel J, Duschka L

Deutsche Klinik für Diagnostik, Wiesbaden Coloproctology, February 2015; 37(1):76

41. Deutscher Koloproktologen-Kongress

OTSC® update 19**February 2014 | Two Studies show efficacy of anchoring esophageal SEMS (self-expanding metal stents) with OTSC**

In a retrospective study of 13 patients, Dr. Irani, Dr. Gluck, Dr. Gan, Dr. Ross and Dr. Kozarek of the Department of

Gastroenterology, Virginia Mason Medical Center, Seattle, Washington, 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 SEMS 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 unanchored stents at 4.0 to 5.6 newton. The paper identifies clips as the least expensive device, but advises that costs associated with the possible use of multiple clips or stent migration should also be taken into account. In conclusion, the authors evaluate the use of OTSC for anchoring of fully covered SEMSs as 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

210

Epub 2014 Sep 30

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

K. Ito, Y. Igarashi, T. Mimura et al., Division of Gastroenterology and Hepatology, Toho University Omori Medical Center, Tokyo, Japan, published a case study on the successful OTSC closure of a colonic fistula complicating severe pancreatitis. Dr. E.C. Gorospe, Dr. S. Desai, Dr. B. Al-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

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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

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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:

Media Contact: Anne Brownsey abrownsey@asge.org

American Society for Gastrointestinal Endoscopy

www.asge.org | www.screen4coloncancer.org

AN OVER-THE-SCOPE CLIPPING DEVICE FOR ENDOSCOPIC MANAGEMENT OF GASTROINTESTINAL DEFECTS IS SAFE AND EFFECTIVE

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 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, multi-center 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 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."

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:

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

Clinical presentations at German Congress on Visceral Medicine confirm efficacy of OTSC clipping and show clinical data on novel Ovesco products FTRD and remOVE Leipzig, September 17–20, 2014.

The 69th annual congress of the German society for gastroenterology, digestive and metabolic diseases, DGVS, was held under the presidency of Prof. Dr. med. Peter R. Galle. A significant number of presentations provided clinical data on OTSC clipping and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistulae (source: www.viszeralmedizin.com).

Conference report

Clinical presentations at German Congress on Visceral Medicine confirm efficacy of OTSC clipping and show clinical data on novel Ovesco products FTRD and remOVE. Leipzig, September 17–20, 2014: The 69th annual congress of the German society for gastroenterology, digestive and metabolic diseases, DGVS, was held under the presidency of Prof. Dr. med. Peter R. Galle.

A significant number of presentations provided clinical data on OTSC clipping and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistulae (source: www.viszeralmedizin.com).

Reports on Ovesco OTSC

OTSC proves to be preferable treatment option for several indications.

Glitsch A, Schreiber A, Boldt J, Keßler W, and Mayerle J, Greifswald, reported about a cohort of 46 patients treated with OTSC clips. The indications include postoperative anastomotic insufficiency (n=13), bleeding (n=7), perforations (n=15), pancreatic fistulae in the colon (n=4), fistulae in patients with inflammatory bowel disease (n=5) and OTSC use after ESD (n=2). Successful closure and complete healing was achieved for all but one indication. In the case of postoperative anastomotic insufficiencies 3 out

of 13 insufficiencies could not be closed successfully (76.93% success rate). These patients had to undergo further laparoscopic treatment. In all other cases (n=43), no complications were observed and thus no further treatment was necessary. The authors declare OTSC to be a procedure with significantly lower morbidity and mortality in comparison to conventional treatment options and emphasize that it spares patients elaborate and more complication-prone methods of treatment.

Retrospektive Auswertung der OTSC Anwendung an der Universitätsmedizin Greifswald

Glitsch A, Schreiber A, Boldt J, Keßler W, Mayerle J

OTSC for stopping acute bleeding in the gastrointestinal tract.

Braun A, Freiburg, and Kirschniak A, Tübingen, presented data about a total of 16 patients (median age=75.5 years, R=61–92 years; m=9, f=7) over three years with acute bleeding, who were treated with OTSC application during emergency endoscopy. 8 procedures were performed in the upper and 8 in the lower gastrointestinal tract. Patients with upper GI bleeding were given a highly dosed proton pump inhibitor (80mg i.v. Bolus, 320 mg i.v./ 24h). Hemorrhages were classified as follows: Forrest Ia (n=7), Forrest Ib (n=7), and Forrest IIa (n=2). All patients suffered an acute drop in hemoglobin and showed definite signs of bleeding. No further local therapies were administered. All OTSC applications were performed by the same clinician and took 20 minutes or less.

OTSC application and thus primary hemostasis was successful in all cases. None of the patient suffered recurrent gastrointestinal bleeding. 6 patients (4 Fla, 1 Fib, 1 FIIa) had a follow-up endoscopy between day 1 and 7; all clips were in-situ with no signs of bleeding. The other 7 patients were not reexamined due to good response to treatment. The authors see OTSC as a safe and very effective treatment option in emergency endoscopy. Primary hemostasis is possible for a large percentage of patients, which improves lethality, and examination time is low.

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

Braun A, Kirschniak A

Interdisciplinary treatment regime for thoracic anastomosis insufficiencies.

Pauthner M, May A, Lorenz D, and Ell C, Offenbach, introduced the complication management regime for thoracic anastomosis insufficiencies (AI) at HSK Wiesbaden hospital. From 07/2000 to 12/2013, they counted 632 cases of resections in the esophagus, 557 of which included transthoracic esophageal resections with intrathoracic anastomosis of a gastric sleeve. 49 of these 557 patients (8.8%) suffered from confirmed AI.

Of these cases, 13 (26.5%) were treated conservatively with a triple-lumen jejunal feeding and gastric decompression tube (TLT), 14 (28.6%) were treated with a primary stent, in 7 patients an OTSC clip was placed endoscopically (14.3%) and 2 (4.1%) received transluminal vacuum therapy. 12 patients (26.5%) had to undergo repeat thoracotomy, 7 of which had a stent placed during the procedure (14.3%). Hospital lethality after all esophageal resections was 3.6%, with only 2.3% in the last 4 years. If gastric sleeve shows good blood circulation and the AI is small, either a clip or a TLT is placed. Routine check after 36–48h. Larger AIs are treated with stents; routine check after 24 h and placement of TLT to protect stent from bile. If pleural empyema occurs, a repeat thoracotomy is performed, including decortication and sewing-over of the AI as well as stent placement; stent is fixated with an absorbable suture. The authors report that this indicationspecific, standardized complication management regime reduced lethality after occurrence of thoracic AI from 14.3% to 3.1%.

Therapie der Anastomoseninsuffizienz nach Ösophagus-Resektion – die viszeralmedizinische Herausforderung

Pauthner M, May A, Lorenz D, Ell C

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

Wedi E, Sportes A, and Hochberger J, Strasbourg, France, presented the case of a 68-year-old patient with a chronic esophageal-bronchial fistula. In early 2010 he presented with haemoptysis and an unidentified pulmonary lesion. Examination of the mediastinum and subsequent exploratory

thoracotomy showed giant-cell granuloma with no indication of malignancy. In December 2011 patient reported repeated incidents of coughing during food intake with recurrent bronchio-pulmonary infections, and an esophageal-bronchial fistula was diagnosed. Initial treatment included a fully covered Nitinol stent (23/18 mm wide, 12 cm long), which dislocated two days after food was reintroduced. In the following 1.5 years, a variety of endoscopic treatment options were explored (partially covered stent, fibrin glue, standard hemoclips, etc.), but all proved unsuccessful while a 5–7 mm wide fistula tract had formed. In collaboration with pulmonologists and thoracic surgeons, an experimental course of treatment was employed. Deep tissue in the fistula tract was excised using endoscopic submucosal dissection (ESD). Then a flexible bronchoscopy with APC and chafing of the fistula tract with a brush was performed. Finally, the fistula tract was closed with a 17.5 mm OTSC macro clip. Preliminary endoscopic-radiological follow-up over a 4 month period has shown no recurrence. The authors conclude that excision of the fistula and subsequent closure with an OTSC macro clip is a promising new treatment option, which should be further evaluated.

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

Wedi E, Sportes A, Hochberger J

Report on Ovesco FTRD (Full-Thickness Resection Device), newly launched by Ovesco Preliminary clinical experience with the FTRD system in the lower gastrointestinal tract.

Schmidt A, Damm M and Caca K, Ludwigsburg, together with Gubler C and Bauerfeind P, Zurich, Switzerland, reported their experience with endoscopic full-thickness resection in the lower GI tract of 21 patients from July 2012 to March 2014. Resection was always performed using the FTRD system mounted onto a standard endoscope. Indications included recurrent or incompletely resected adenoma with non-lifting sign (n=9), adenoma with high-grade prostate intraepithelial neoplasia (HGPIN) (n=1), adenoma on base of appendix (n=3), broad-based adenoma in patient with coagulation disorder (n=1), diagnostic (re-)resection in patients with T1 carcinoma (n=3), adenoma on diverticulum (n=1), a submucosal tumor (n=2), a diagnostic FTR for a patient with suspected Hirschsprung's disease (n=1). Lesions were located in the cecum (3), ascending colon (4), transverse colon (2), descending colon (4), sigma (2), recto-sigmoid (3), and rectum (3). Navigation to target lesion with FTRD mounted onto endoscope was possible in all but one case (95.2% success rate).

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

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

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

Report on OTSC Proctology

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

Prosst R presented the experiences of a prospective pilot study at St. Anna hospital, Stuttgart, and edz center of excellence in proctology, Mannheim, regarding the use of OTSC Proctology. The study included 20 patients (14 male, 6 female), aged 56.1 years on average (R 25–73 years). There were 14 transsphincteric and 6 suprasphincteric anorectal fistulae. Average procedure time for clipping of fistulae was 32 minutes (R 17 to 66 minutes). There were no intraoperative complications. Follow-up endoscopy after six months or more showed proper healing in 18 of 20 cases (90% success rate). The

clip had remained in-situ in 13 patients. The clips fell off spontaneously (10 to 4 days post-op) in three patients. The clip was surgically removed in two patients (clip dislocation, severely impaired wound healing). The fistula persisted/recurred in two of 20 cases (10%). Reasons were spontaneous clip displacement on day 3 post-op and failure to heal. In the second case, the clip was removed and another loop was placed.

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

OTSC ohne Endoskop: Anorektaler Fistelverschluss mittels OTSC Proctology

Prosst R

(cf. Prosst RL, Joos AK, Ehni W, Bussen D, Herold A Prospective pilot study of anorectal fistula closure with the OTSC | Proctology. Colorectal Dis. 2014 Sep 1. Epub)

Report on remOVE System

(product approval in Europe pending)

Early clinical data on new bipolar DC cutting instrument for OTSC clips show efficacy and safety.

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

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

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

October 2014 | ESGE Position Statement on the treatment of endoscopic perforations: OTSC endorsed as preferential device.

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

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

For colonic perforations the guideline states that OTSC is the preferential device for larger lesions. Only small holes can be treated with conventional clips.

For the complete list of recommendations by ESGE please

check the resources linked at the bottom of this news message.

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

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

Paspatis GA, Dumonceau JM, Barthel M, Meisner S, Repici A, Saunders BP, Vezakis A, Gonzalez JM, Turino SY, Tsiamoulos ZP, Fockens P, Hassan C

Endoscopy. 2014 Aug;46(8):693-711 doi: 10.1055/s-0034-1377531

Epub 2014 Jul 21. Free paper (download German version)

ESGE: www.esge.com/esge-guidelines.html

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 enterocutaneous fistula.

The first New York case was an 80-year-old female with dysphagia, history of aortic valve regurgitation, esophageal perforation due to TEE, repair with feeding jejunostomy and venting gastrostomy. Healing resulted in a 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 (> 1cm) was to blame for inefficient healing.

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

75

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

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 clips the patient was discharged but presented with worsening symptoms. Another EGD showed a persistent fistula that was finally closed with an OTSC clip resulting in a complete healing.

The other patient (71-year old woman) presented with hypotension, melena and low hemoglobin level 3 weeks after 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:E343-4 146

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):546 147

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

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OTSC® update 17

June 2014 | Spanish researchers receive award for successful OTSC case presented at the National Digestive Congress Spain, June 14–16, 2014 in Valencia

D. López Peñas and colleagues, Servicios de A. Digestivo, Otorrinolaringología y Oncología médica, Hospital de Llerena, Spain received an award for their presentation at the Semana de las Enfermedades Digestivas (SED 2014) in Valencia.

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

Here you can see the presentation (in Spanish):

http://www.ovesco.com/fileadmin/Downloads/Flyers_for_events/2014_National_Digestive_Congress_Spain.pdf

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 gastrointestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was successfully deployed.

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

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

Novel treatment of a 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. 129

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 | [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):606-8 101

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

Recently Mönkemüller et al. from Birmingham, AL, USA report the analysis of an observational retrospective case series of 16 patients (median age 65.8 years) with mixed indications for the treatment with the OTSC System. The

overall success rate of 75% is 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 esophago-pulmonary 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 an 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):350-7 133

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 Verschluss-techniken

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 Top papers

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 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, Nägele A, Hagel A, Rösler W, Förtsch T, Neurath MF, Raithele 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%), post-interventional 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 a. M., 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

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

Anorektaler Fistelverschluss mittels OTSC Proctology: Ergebnisse einer prospektiven Beobachtungsstudie

R. Probst, 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

Departments of General and Visceral Surgery, Rotes Kreuz Krankenhaus, Kassel and University Hospital, Goettingen

R. Menningen 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. Menningen, 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.

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 restarted after 2 or 5 days, respectively.

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

Salord S, Gornals JB, Maisterra S, Pons C, Busquets J, Fabregat J

Rev Esp Enferm Dig. 2012 Sep;104(9):489-90 98

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

Donatelli G, Vergeau BM, Dritsas S, Dumont JL, Tuszyński T, Meduri B

Endoscopy. 2013 Nov;45 Suppl 2 UCTN:E392-3 151

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 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

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;

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

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-jejunoanastomosis.

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):749-56 128

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 Endoscop. 2013; 27:2258-74 81-2

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 Epub 2012 Jun 14 113

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

126

OTSC® update 16**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

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 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

Díez-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

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 | 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.

120

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, colcutaneous, enterocutaneous, 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 postoperative 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

115

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

114

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

Postoperative leaks after total gastrectomy are among the most common early complications. Dr. C. N. Ferreira and colleagues, Serviço de Gastroenterologia e Hepatologia, Hospital de Santa Maria, Lisbon, Portugal report on a 78-

year old woman presenting with melena. She was diagnosed with gastric adenocarcinoma and treated with total gastrectomy and 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 ;
[Epub 2013 Jan 4]

112

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

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OTSC® update 15 EXTRA

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

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

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

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

Endoscopy. 2012;44 Suppl 2 UCTN:E412-3.
[Epub 2012 Nov 20]

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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 by-pass (n=2), esophageal perforation (n=3).

Three of the four patients with gastric leaks had undergone previous unsuccessful attempts at endoscopic repair (stenting, fibrin glue application, traditional clipping, endoscopic suturing). The overall clinical success rate was 70%. Re-surgery was needed in the two cases of gastro-gastric 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]

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

The two case reports published in the journal Digestive Endoscopy by Dr. Hirohito Mori and his colleagues, 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, Miichi N, Suzuki Y, Masaki T
Dig Endosc., 2013 Jul;25(4):459-61 | Epub 2012 Aug 7

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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 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, Vaizy C, Bashir G, Hansmann A, Gupta A, Konieczko K, Fraser C
Gastrointest Endosc. 2012 Apr;75(4):893; discussion 894

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

Mönkemüller K, Peter S, Alkurdi B, Ramesh J, Popa D, Wilcox C
World J Gastrointest Endosc. 2013 Aug 16;5(8):402-6

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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 endoscopic over-the-scope clip

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

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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]

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OTSC® update 14

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

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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 | Epub 2012 Aug 22

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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

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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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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 premounted with a specially designed, derivative OTSC clip and the cap incorporates a resection snare.

Prof. Rösch grasped the lesion with a grasping forceps and pulled the target tissue into the cap in a full thickness fashion. After mobilizing the tissue into the cap, the clip was released to seal the invaginated tissue before resection. Right afterwards the snare was closed and the tissue resected with HF current.

The resection specimen included the full thickness of the wall carrying the NET, with a safety margin. The serosa was seen in histology, confirming that the specimen was a full-thickness resection.

The FTRD device is not yet commercially available.

endo-update 2012 | 30.11.-01.12.2012

Venue: Klinikum Augsburg, Augsburg, Germany

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

Dr. 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

Epub 2012 May 17

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OTSC® update 13

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

In this first trial from China (after compassionate use cases in patients earlier on) the authors investigated the feasibility of the OTSC System for the closure of gastric perforations in the fundus. This location is of special interest since the handling of a flexible scope in the retroflex position is sometimes quite challenging. The investigation was done in a dog model. The perforation was performed with 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 methylene blue solution resulted in one minor leak (laparoscopic control) without clinical consequences though. The authors conclude that the OTSC System is safe and appropriate for the closure of acute perforations in the stomach despite the well known difficulties with the J-maneuver.

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

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

J Gastroenterol Hepatol. 2012 Jul;27(7):1200-4

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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

rebleeding (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 done for recurrence of 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 et al., Tübingen

OTSC to prevent migration of covered self-expanding stents

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

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

Hagel A, Nägel A, Raitheil S, Diebel H, Neurath M, and Raitheil 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 comorbidities 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, Neubrandenburg

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

Kratt T, Stüker D, Kirschniak A, Heining 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 rebleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was the only therapy. In the other patients OTSC was a successful "bridge to surgery" and allowed stabilizing the patient before the operation.

OTSC-basierte Notfall-Hämostase der lebensbedrohlichen A. gastroduodenalis Ulkus-Arrosionsblutung: alleinige endoskopische Therapie oder „bridge-to-surgery“

T. Kratt, D. Stüker, A. Kirschniak, A. Heining, 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

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. Probst, 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 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. Probst, Stuttgart, coordinator of the trial, summarized that data were encouraging but completion of the trial had to be awaited. The trial is expected to close in 2013.

www.mcn-nuernberg.de/DGK2013/programm-08032013.php

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 endosonographic 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

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, abridement 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]

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

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

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]

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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 post-operative anastomotic leak in the esophagus. However, the stent partially migrated into the stomach. The stent was then repositioned onto the leak. The OTSC System was placed using the OTSC Twin Grasper to grasp the stent edge and suction. After application the OTSC clip fixed the stent to the esophageal wall. Follow-up showed successful closure of the anastomotic leak.

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

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

Toshniwal J, Zabielski M, Fry LC, Mönkemüller K
Endoscopy. 2012;44 Suppl 2 UCTN:E288-9

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, Saşmaz N
Clin Res Hepatol Gastroenterol. 2012 Dec;36(6):614-21 [Epub 2012 Jun 14]

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, Orditura 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]

December 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 years in the past.

Cholangiography showed a bile duct stricture. An endoscope-related perforation of the jejunum with a size of about 20 mm was visualized distally of the papilla. After placing a covered self-expanding stent through the biliary duct 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, Dizioli P, Staiano T

Gastrointest Endosc. 2012 May;75(5):1115-7 [Epub 2011 Aug 5]

November 2012 | First publication of Japanese experience with OTSC®

In the recent issue of the World Journal of Gastroenterology 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

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

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

Prof. Dr. Alberto Arezzo and colleagues, Dept of Digestive, Colorectal and Minimal Invasive Surgery, University of Turin, Italy report about a prospective case series covering 14 consecutive patients, treated between April 2008 and September 2011. Criteria for treatment with OTSC were a wall opening of <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 Nov;26(11):3330-3

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)

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

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

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,