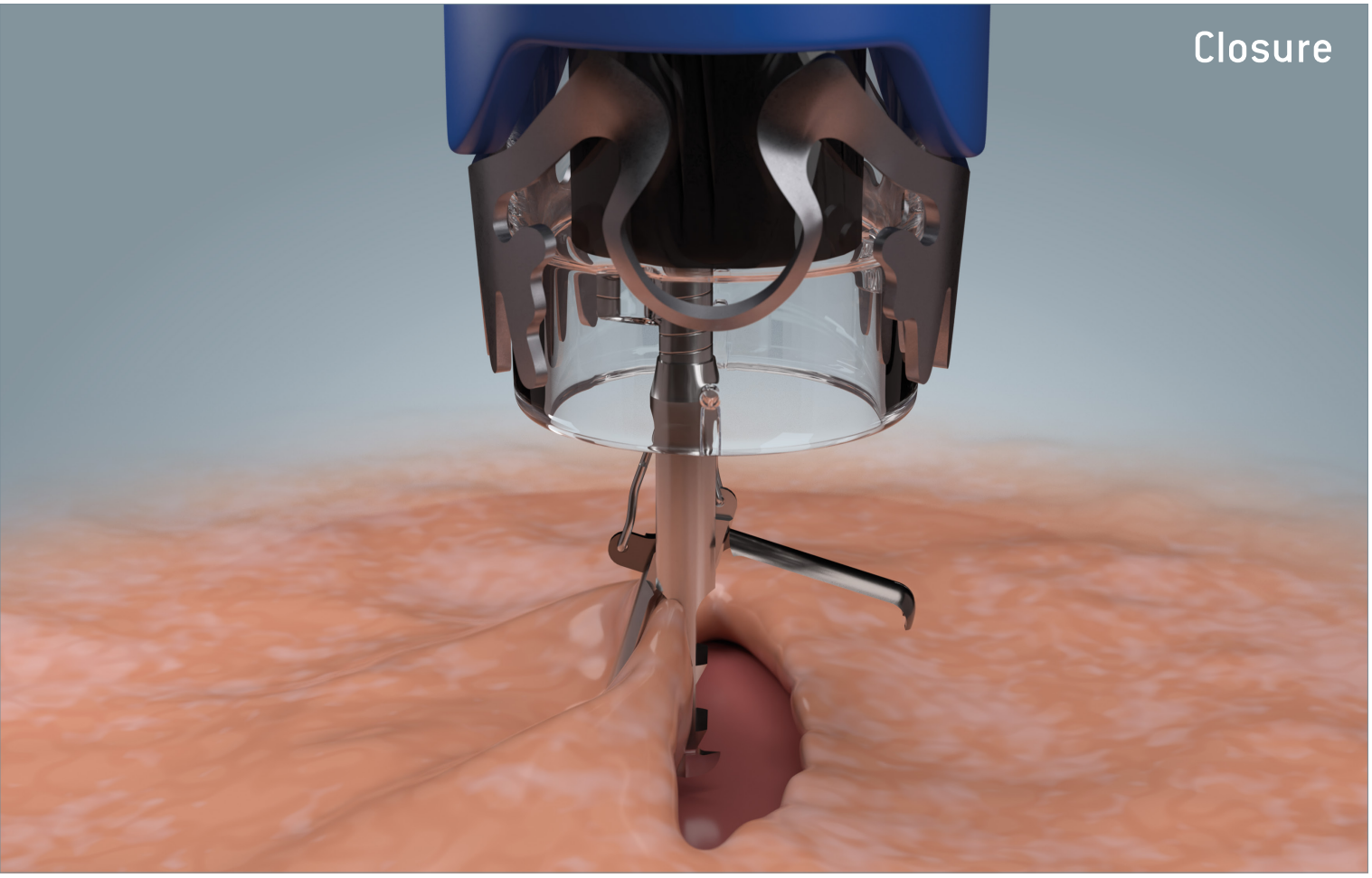


clinical bulletin

OTSC®neo
for endoscopic closure

The OTSC®neo System

OTSC® – The best-studied closure device

Numerous studies demonstrate the high efficacy of OTSC® for closure of lesions, leaks, and fistulas.

With over 200 studies, OTSC® is the most extensively investigated instrument for defect closure in the gastrointestinal tract. OTSC® demonstrates high efficacy and reliability for acute lesions, fistulas, and leaks as well as a preventive measure after resections.

OTSC®neo represents the evolution of the clinically proven OTSC® System based on feedback from users worldwide. The scientifically proven efficacy remains unchanged, while application and handling have been optimized for clinical practice.

Overview of the OTSC®neo System

The OTSC®neo System is a proven product used in flexible endoscopy for closure of acute and chronic lesions, leaks, and fistulas, as well as for hemostasis.

OTSC®neo consists of a transparent application cap with preloaded Nitinol® clip, a release thread, a thread retriever, and a handwheel for clip application. Application of the OTSC®neo System is simple and quick. The procedure combines the following advantages:

- Optimal for deep perforations through **full-thickness closure**
- Multifunctional for various defects: **perforations, leaks, and fistulas**
- Reduction of surgical interventions and lower patient burden through **effective endoscopic treatment**



Features and sizes of OTSC®neo application caps and clips

The OTSC®neo System is available in various cap sizes and clip designs to ensure **secure closure regardless of anatomical situation** and endoscope type. For closure in the upper GI tract, cap sizes mini, 11, and 12 are used; cap size 14 is typically used for colonoscopes.

The OTSC®neo application cap provides distance between the endoscope tip and the digestive tract wall. This distance enables **good endoscopic visualization** and allows the cap to **encompass sufficient tissue**. Through suction and flushing, the OTSC®neo cap can thus support tissue cleaning and simplify visualization of the wall defect.

The various cap sizes correspond to the maximum diameters of usable endoscopes and enable appropriate cap selection according to the respective anatomical situation. The **deep cap (6 mm)** is primarily used for endoscopic closure. This allows the user to **retract a larger amount of tissue** and close it with the clip. The “mini” size is designed for difficult-to-access locations and also fits pediatric endoscopes.

Auxiliary instruments: OTSC® Anchor and OTSC® Twin Grasper®

The two auxiliary instruments, OTSC® Anchor and OTSC® Twin Grasper®, support closure in different locations and conditions to ensure the best possible closure.



The OTSC® Anchor improves tissue mobilization even under difficult conditions such as scarring (e.g., fistulas, ulcer base). Conventional graspers tend to slip off tissue; the Nitinol® anchor needles, however, spread in the tissue, allowing better tissue grip.

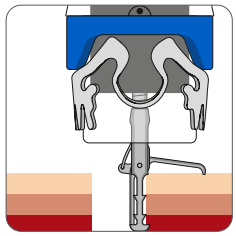
The OTSC® Twin Grasper® facilitates approximation of wound edges of a lesion. The two jaw parts can be opened independently, allowing opposing edges of lesions to be grasped and mobilized into the OTSC® cap.

Application techniques

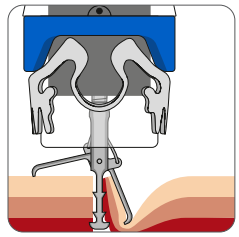
Practical application of the OTSC®neo System for endoscopic closure

Perforation closure with the OTSC® Twin Grasper®

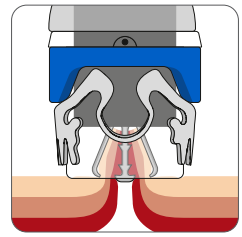
The OTSC® Twin Grasper® application aid supports controlled closure of lesions through its two jaw parts. The opposing wound edges can be grasped with one jaw part each and approximated. Subsequently, the tissue can be mobilized into the cap and the perforation closed with the OTSC®neo clip. This enables full-thickness closure.



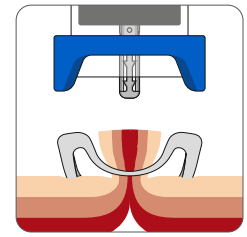
Grasp the first wound edge with one of the jaw parts of the OTSC® Twin Grasper®.



Grasp the opposing wound edge with the other jaw part



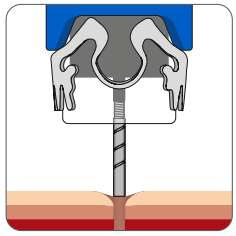
Retract the perforation into the cap (OTSC® Twin Grasper® must be completely in the cap).



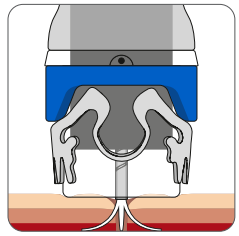
Clip application and release of the OTSC® Twin Grasper® from the tissue.

Fistula closure

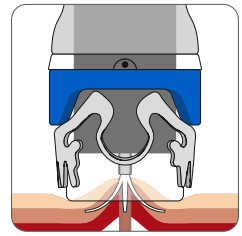
OTSC®neo is also suitable for closure of gastrointestinal fistulas (e.g., PEG fistulas). The OTSC® Anchor facilitates mobilization of the fistula opening into the cap. By refreshing/débriding the tissue at the fistula and fistula tract, it can heal better after closure.



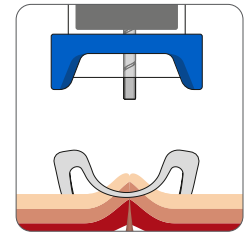
Target the fistula entrance and apply the OTSC® Anchor to the fistula opening.



Approach the cap and gently pull the tissue.



Mobilize the OTSC® Anchor shaft into the cap; the anchor tips can remain outside.



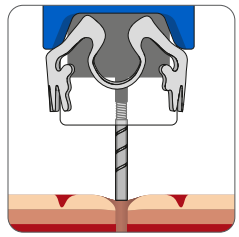
Deploy the clip and release the OTSC® Anchor from the tissue.

Optimized fistula closure

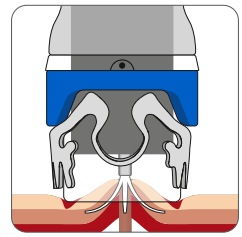
Optimized fistula closure* using mucosal incision can achieve good treatment results in therapy-resistant fistulas. The circular incision at the mucosa before closure with the OTSC®neo clip can reduce tissue tension around the fistula opening and lead to more effective tissue compression by the clip. The tissue in the fistula tract should be refreshed to promote healing.



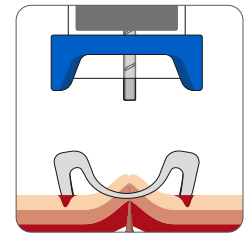
Circular mucosal incision around the fistula opening (Ø ~ 15 mm).



Target the fistula entrance and apply the OTSC® Anchor to the fistula opening.



Place the clip in the incision line.



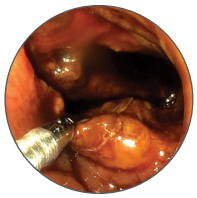
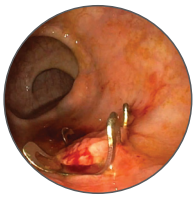
Apply the clip and close the fistula.

*Prof. Dr. med. A. Meining, Department of Internal Medicine II, Gastroenterology, University Hospital Würzburg, Germany

Case examples

OTSC® Clip placement for closure of gastrointestinal defects and lesions

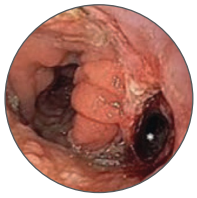
Defect/Lesion | Treatment outcome

Traumatic rectal perforation

A patient suffered an approximately 30 mm traumatic perforation in the rectum that was treated endoscopically with the OTSC® System. Using the OTSC® Twin Grasper®, the wound edges were precisely captured and a secure transmural closure was achieved.

Source: Dr. M. Manno & Dr. P. Soriani, UOSD Endoscopia Digestiva Area Nord, Azienda USL di Modena, Italy




Anastomotic insufficiency after gastrectomy

A patient developed anastomotic insufficiency after gastrectomy, which was treated with combination therapy of endoscopic vacuum therapy (EVT) and OTSC®. First, EVT was used to largely close the leak and build up granulation tissue (left image). Then an OTSC® clip was placed to completely close the remaining residual lumen of approximately 1 cm (right image).

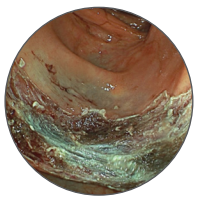
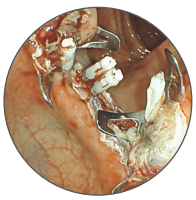
Source: Kollmann et al., 2024[5]




Esophago-tracheal fistula in actinomycosis

A patient with actinomycosis presented with two fistulas (left image): an esophago-esophageal fistula (left) and an esophago-tracheal fistula (right). The esophago-tracheal fistula was specifically treated by mechanical destruction of the fistula tract, APC treatment of the esophageal-side fistula ostium, and subsequent OTSC® closure. After 4 weeks, complete healing of the esophago-tracheal fistula was observed, while the esophago-esophageal fistula remained asymptomatic (right image).

Source: Prof. Dr. D. Anz, Department of Internal Medicine II, LMU Klinikum, Munich, Germany

Large-scale ESD in the rectum

After large-scale ESD of a lesion in the rectum (left image), prophylactic wound closure was performed to prevent delayed bleeding and perforations. The extensive resection area was systematically closed using OTSC® and conventional endoclips (right image).

Source: PD Dr. E. Wedi, Department of Internal Medicine II, Gastroenterology, Gastrointestinal Oncology & Interventional Endoscopy, Sana Klinikum Offenbach, Germany

Follow-up and MR conditionality

Once an OTSC®neo clip is successfully deployed it **will stay in situ for several weeks to several months.** The exact duration depends on the amount and texture of the tissue secured. The OTSC®neo clip **will leave the GI tract naturally** in the majority of cases. Occasionally, it may be overgrown by mucosa and remain in the body as a **long-term implant**, which is no problem because of its design and **biocompatibility.** In rare cases, in which a clip removal is necessary, e.g. local complication or misplacement, the OTSC®neo clip can be easily removed with the **Ovesco remOVE System.** This gives you the option to reverse or repeat the procedure.

MR conditionality

The OTSC®neo clip is MR conditional. Patients can be scanned safely in an MRI system after OTSC®neo clip placement under the following conditions: a) **static magnetic field of 3 Tesla or less, b) maximum spatial gradient magnetic field of 4,000 gauss/cm** (40 T/m). For further details, please refer to the instructions for use.

Clinical evidence

OTSC®neo expands the possibilities of endoscopic defect closure

1. Closure of perforations

OTSC® enables secure endoscopic closure of acute, iatrogenic perforations using full-thickness technique and avoids surgical interventions in the majority of cases. Particularly in combination with the OTSC® Twin Grasper®, consistently high clinical success rates are achieved. This led to the inclusion of OTSC® in international guidelines.

High clinical success in acute, iatrogenic perforations through full-thickness technique

As early as 2012, Voermans et al. examined 36 consecutive patients with acute, iatrogenic perforations < 3 cm in a prospective, multicenter study. The overall clinical success rate was 88.9% (32/36; 95% CI, 75–96%). In these cases, the OTSC® Twin Grasper® was used to approximate perforation edges and achieve full-thickness closure. This OTSC® treatment proved comparatively quick and simple, enabling adequate closure without surgical intervention in 88.9% of patients. The mean closure time was 5 minutes and 44 seconds.[1]

Comprehensive evidence from systematic review: High success rates and reduction of surgical interventions

In the systematic review by Bartell et al., 85 studies with 3,025 patients treated with OTSC® for various indications were analyzed. For perforations, a technical success rate of 95.5% (447/468) and a clinical success rate of 85.3% (399/468) were achieved (Fig. 1A). Only 9.4% (44/468) of patients required surgical intervention after OTSC® placement. The authors concluded that OTSC® enables effective endoscopic treatment of iatrogenic complications and complex defects that previously often required surgical intervention.[2]

Significantly decreased surgery rate since introduction of the OTSC® System

As Bartell et al. already concluded, the clinical relevance of OTSC® is particularly evident in the reduction of surgical interventions[2]. The study by Khater et al. also confirms this. They compared the surgery rate before and after introduction of the OTSC® System in a total of 40 iatrogenic perforations (Fig. 1B). While 62.5% (15/24) of perforations had to be treated surgically before availability of the OTSC® System, this rate decreased significantly to 12.5% (2/16; p = 0.002) after introduction of the system. The mortality rate decreased from 8.3% (2/24) to 0% (0/16; p = 0.23).[3]

Establishment of OTSC® in international guidelines

The comprehensive clinical evidence led to the inclusion of OTSC® in ESGE guidelines in 2020. These recommend the use of OTSC® for perforations (> 10 mm, but < 20–25 mm).[4]

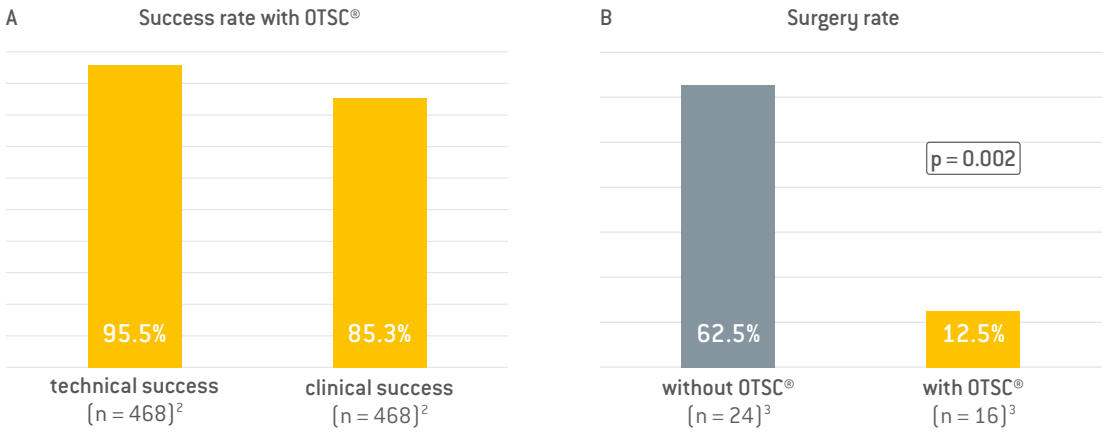


Figure 1: Perforation closure with OTSC® – (A) Technical and clinical success (Bartell et al., 2020) and (B) surgery rate (Khater et al., 2017)

Clinical evidence

2. Closure of leaks

OTSC® shows high success rates in closure of postoperative anastomotic and suture leaks. Particularly in combination with complementary endoscopic procedures such as endoscopic vacuum therapy (EVT), OTSC® optimizes treatment outcomes.

Effective treatment of bariatric surgery leaks

The systematic review by Shoar et al. evaluated the efficacy of the OTSC® System for leaks and fistulas after laparoscopic sleeve gastrectomy (LSG). The analysis included 10 studies with 195 patients. Of 73 patients with LSG leaks, successful closure was achieved in 63 (clinical success rate 86.3%).[5]

Shortened therapy duration with improved oral nutrition through combination therapy EVT + OTSC®

Kollmann et al. demonstrated the advantages of combining OTSC® with EVT in a total of 84 patients with postoperative upper GI leaks. The clinical success rate was 100% (42/42) in both groups (Fig. 2A). However, additional OTSC® placement led to a significant shortening of therapy duration compared to EVT alone (33 vs. 46 days, p = 0.004; Fig. 2B). Additionally, 98% (41/42) of patients in the EVT+OTSC® group could be sufficiently orally fed at discharge, compared to 60% (25/42) in the EVT group (p < 0.001; Fig. 2C).[6]

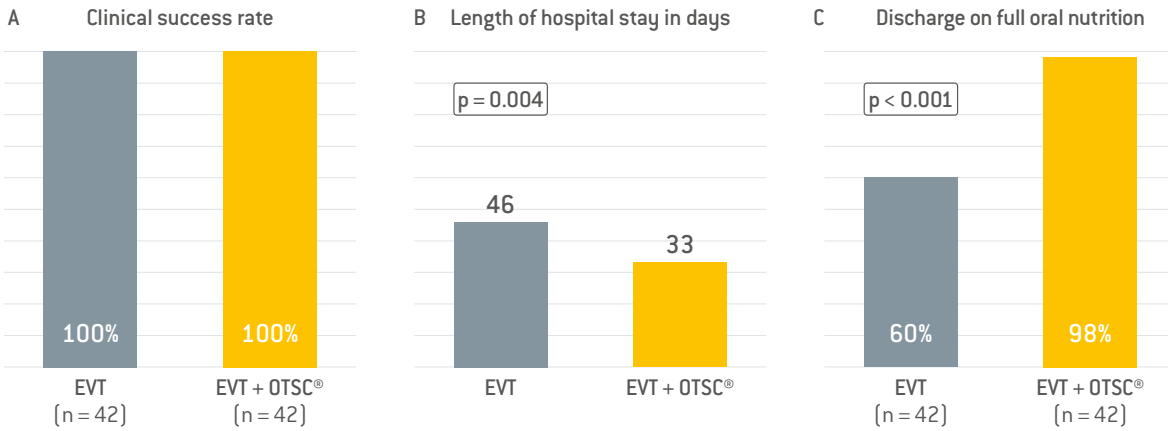


Figure 2: Effect of combination therapy (EVT+OTSC®) vs. EVT alone on postoperative UGI leaks - (A) Clinical success, (B) hospitalization and (C) discharge on full oral nutrition (Kollmann et al., 2024)

3. Fistula closure

OTSC® offers a promising solution for the closure of chronic fistulas, with the success rate being significantly increased through tissue preparation.

Good success rates in heterogeneous fistula populations

The systematic analysis by Bartell et al. also included 622 patients with gastrointestinal fistulas of various etiologies. The technical success rate was 92.8% (577/622), the clinical success rate was 55.8% (347/622). For prospective studies, however, a higher clinical success rate of 70.3% (71/101) was observed.[2]

High clinical and technical success in persistent gastrocutaneous fistulas through targeted tissue preparation

Vella Baldacchino et al. demonstrated the importance of tissue preparation in an observational study on gastrocutaneous fistulas. In 31 patients with persistent gastrocutaneous fistulas after PEG (percutaneous endoscopic gastrostomy) removal, the fistula tract was first pretreated with an abrasive fistula brush. The technical success rate was 97%, the clinical success rate reached 94% both after 30 and 90 days (Fig. 3). The median procedure duration was 14 minutes (range 9–35 min).[7]

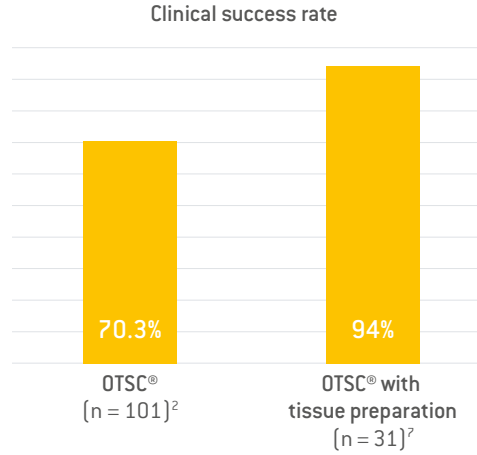


Figure 3: Fistula closure with OTSC® – Clinical success (Bartell et al., 2020; Vella Baldacchino et al. 2024)

Clinical evidence

4. Preventive clipping after complex endoscopic resections

OTSC® can reduce the risk of delayed bleeding and perforations as a preventive measure after endoscopic resections.

Clinical benefit of OTSC® as prophylaxis after complex colonoscopic resection

Blasberg et al. evaluated prophylactic OTSC® placement after complex endoscopic submucosal dissection (ESD) and endoscopic mucosal resection (EMR) of large colon polyps. In 73 patients, the OTSC® group showed a technical success rate of 100% (73/73) and a clinical success rate of 98.7% (72/73; Fig. 4). Delayed bleeding occurred in only 1.4% (1/73), delayed perforations in 0% (0/73).[8]

OTSC® as prophylaxis for larger mucosal defects after duodenal ESD

Jinushi et al. compared conventional clips with OTSC® for closure of mucosal defects after duodenal ESD in 82 patients. In the OTSC® group (n = 55), the complete closure rate was 98.2% (54/55). Delayed bleeding occurred in only 3.6% (2/55), delayed perforations in 0% (0/55), resulting in a clinical success rate of 96.4% (53/55) (Fig. 4). The authors recommend OTSC® for mucosal defects > 18 mm, while conventional clips are suitable for smaller defects ≤ 18 mm.[9]

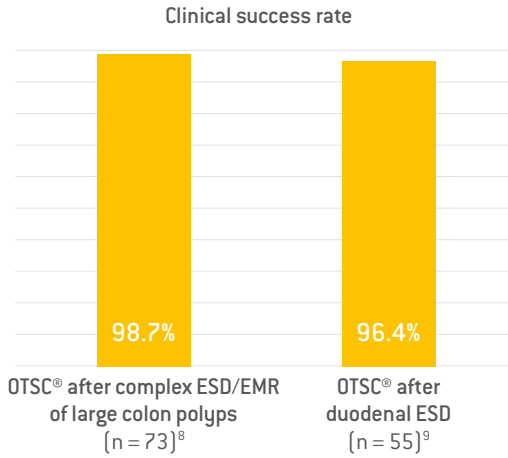


Figure 4: Preventive clipping with OTSC® – Clinical success (Blasberg et al., 2023; Jinushi et al., 2023)

5. Fixation of stents, e.g., for larger GI defects

The stentFIX System based on OTSC® technology can significantly reduce migration of stents, which can also be used for closure of GI defects.

More information on the stentFIX System

For example, the systematic review by Jena et al. with 9 studies and 182 patients shows that stents fixed via OTSC® technology have a significantly lower migration rate than non-fixed stents (RR = 0.24; 95% CI 0.13–0.43). The pooled migration rate with OTSC® fixation was 10% (95% CI, 4–20%).[10]

Summary

OTSC® consistently achieves high success rates and avoids surgical interventions for GI defects

The OTSC® technology, already clinically proven in hemostasis, also enables safe treatment of gastrointestinal defects through transmural closure. The comprehensive clinical evidence demonstrates:

- **High clinical success rates in closure of acute perforations** with OTSC® and OTSC® Twin Grasper
- **Recommended use of OTSC®** for perforations according to ESGE guideline
- **Optimized treatment outcomes and shortened hospitalization** through combination therapy EVT + OTSC®
- **High success rate in fistula closure**, especially with prior targeted tissue preparation
- **Reduction of delayed bleeding and perforations** as a preventive measure after complex endoscopic resections

» OTSC®neo offers patients clinically relevant & scientifically proven benefits – in the areas of defect closure and hemostasis.

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