clinical evidence

Cost-effectiveness analysis

The clinical data of OTSC® are based on two multicenter studies. The data show that OTSC® achieves higher success rates and reduces costs compared to traditional therapy. The ICER (OTSC® therapy vs. former standard therapy) is €589 for overall treatment and €329 for hemostasis.

Further reading

Other clinical bulletins:


OTSC® provides a clinically relevant benefit for patients with bleeding in GI hemostasis.

Further reading

1. Wedi E, Fischer A, Hochberger J, Jung C, Orkut S, Richter-Schrag HJ. Multi-center randomized controlled STING trial 2, Kuellmer
The OTSC® Anchor is available in two sizes, see figures below. In contrast to the OTSC® Anchor 165, the OTSC® Anchor 220tt has shorter prongs.

In cases of fibrotic or hard tissue (e.g. callous ulcers) or tangential application, the OTSC® Anchor can be valuable in precisely aligning target tissue with the cap opening and keeping it fixed during clip release. It may not always be possible to manipulate fibrotic tissue fully inside the application cap.

In most GI bleeding situations, tissue can be mobilized and securely pulled inside the application cap by simply applying endoscopic suction. OTSC® Anchor 165 (thick tissue) OTSC® Anchor 220tt (thin tissue)

Spurring arterial bleeding from peptic duodenal ulcer

The image shows the OTSC® Anchor in spurring arterial bleeding. Follow-up shows that the patient had a full recovery and was discharged 5 days after OTSC® deployment without any symptoms of recurrence after 2 months. The study included 10 patients with duodenal ulcer bleeding. The success rate was 90% (9/10) with no complications. The median length of hospital stay was 4 days.

Dosing bleeding from Ulcer Duodenum

A 55-year-old patient with a duodenal ulcer was operated on after blood transfusions. Two hours after the endoscopic treatment, the patient was discharged after endoscopy with no additional bleeding. Follow-up 2 years after OTSC® deployment showed no bleeding recurrence.

Formation of bleeding from peptic duodenal ulcer

The image shows the OTSC® Anchor in formation of bleeding from peptic duodenal ulcer. The patient had a successful endoscopic treatment with the OTSC® Anchor, performing endoscopic hemostasis of the duodenal ulcer. The patient was discharged without any symptoms of recurrence after 2 days.

Preoperative colonic anastomotic bleeding

Endoscopy of a 52-year-old patient revealed anastomotic bleeding from the distal colonic anastomosis. The patient was operated on with OTSC® deployment and endoscopic hemostasis. Follow-up 3 weeks after OTSC® deployment showed no bleeding recurrence.

OTSC®-cl placement in case of hemorrhage

Suctioning the tip of the OTSC® Anchor into the target tissue

Mobilizing the tip of the OTSC® Anchor into the target tissue

Positioning the OTSC® Anchor and fixing the tissue

Contact the OTSC® Anchor shaft into the target tissue

Suction the target tissue

Release the OTSC® clip

Apply the OTSC® clip

Fix the tissue with the cap opening and keeping it fixed during clip release

Tissue will remain external; the OTSC® 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.

Recent study results show that the OTSC® System is particularly suitable for hemostasis. The prospective multicenter STING trial determined that treatment with OTSC® leads to a significant reduction in re-bleeding compared to standard therapy. The results of this trial (Table 3) showed that treatment with OTSC® System significantly reduced the probability of in 8.3 % (Table 1).

Table 3: Over the Scope Clips Are More Effective Than Standard Endoscopic Therapy for Patients

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>FLETRock</th>
<th>OTSC® System</th>
<th>Rockall</th>
<th>n</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3</td>
<td>7.0</td>
<td>33.0</td>
<td>0.0</td>
<td>1</td>
<td>n.a.</td>
</tr>
<tr>
<td>≥4</td>
<td>53.2</td>
<td>21.4</td>
<td>&lt;0.001</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥5</td>
<td>50.0</td>
<td>20.0</td>
<td>&lt;0.001</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Clinical success 87.5 %

Observed mortality of patients, in whom the OTSC® was used as a first-line therapy was 2.5 % (95 % CI = 0.67–4.33). The median length of hospital stay was four days.

In the prospective multicenter STING trial determined that treatment with OTSC® leads to a significant reduction in re-bleeding compared to standard therapy (84.8 % vs 42.4 %; p = 0.001).

Follow-up

Some patients (10) were successfully discharged in a functional and emotional bowel functional recovery. The study included 10 patients with duodenal ulcer bleeding. The success rate was 90% (9/10) with no complications. The median length of hospital stay was 4 days.

The OTSC® is a safe and effective device for treating patients with severe upper GI bleeding. The study included 10 patients with duodenal ulcer bleeding. The success rate was 90% (9/10) with no complications. The median length of hospital stay was 4 days.

In total, 118 patients (median age of 73.5 years) were included in the study. The prospective multicenter STING trial determined that treatment with OTSC® leads to a significant reduction in re-bleeding compared to standard therapy (84.8 % vs 42.4 %; p = 0.001).

FLETRock

The FLETRock evidence database that the OTSC® therapy is more effective than standard therapy for patients with recurrent bleeding. The study included 10 patients with duodenal ulcer bleeding. The success rate was 90% (9/10) with no complications. The median length of hospital stay was four days.

Large multicenter trial

Analysis of 282 consecutive patient cases showed that the OTSC® platform is an effective in-line therapy for endoscopic hemostasis in patients with recurrent bleeding. The results of this trial (Table 3) showed that treatment with OTSC® System significantly reduced the probability of re-bleeding or continuous bleeding compared to standard therapy (84.8 % vs 42.4 %; p = 0.001).

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Surgical application of the OTSC® System for hemostasis

**Anchor technique**

In cases of too little tissue (e.g., vessels, sites of angiodysplasia), OTSC® Anchor can be used to provide angling during the grasping and sealing for the closure. The tissue should be mobilized to the cap. In this situation, the OTSC® Anchor provides a guide for subsequent OTSC® clip placement.

**OTSC® clip placement in case of hemorrhage**

**Blushing**

- Saturate the tissue with saline solution using the OTSC® Rinser.
- Bring the OTSC® in contact with the tissue.
- Turn the tissue into the cap.
- Pull the tissue firmly to the rim of the cap with the OTSC® Anchor. Then, apply the OTSC® clip.
- The clip “jumps” slightly into the cap.

**Treating result**

- The target tissue is captured inside the cap. Hemostasis is achieved by turning the handwheel to release the OTSC® clip around the cap.

**Clinical evidence**

The clinical efficacy of OTSC® has been documented in a range of peer-reviewed scientific publications over many years. A systematic literature analysis of recent study results shows that the OTSC® System is particularly suitable for hemostasis.

- The OTSC® System is superior to other techniques in GI hemostasis.
- The OTSC® System is more effective than the standard therapy for patients with acute upper gastrointestinal bleeding.
- In a large multicenter trial, patients allowed to cross over to OTSC® treatment. The results of this study showed a significant difference, but a strong trend that OTSC® is more effective than standard therapy (p<0.011).

**Clinical evidence**

<table>
<thead>
<tr>
<th>Clinical evidence</th>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

**Follow-up**

- The patient successfully discharged on the 4th day with a normal hemostatic clinical condition.

**Case example**

Spurting arterial bleeding from peptic duodenal ulcer

- The images show the OTSC® treatment of a spurting arterial bleeding (Forrest Ia) from a duodenal ulcer.
- The patient was released and immediate hemostasis was achieved.

**Medical evidence**

- The images show the prophylactic use of the OTSC® System in patients with acute upper gastrointestinal bleeding. The OTSC® System successfully seals blood vessels and varices.

**Table 1: Multicenter evaluation of first-line endoscopic treatment with the OTSC in acute non-variceal upper gastrointestinal bleeding and comparison with the Rockall cohort: the FLETRock meta-analysis**

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>Number of patients</th>
<th>Observed mortality</th>
<th>Technical success</th>
<th>Clinical success</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3</td>
<td>132</td>
<td>0 (0–70.8)</td>
<td>0 / 3</td>
<td>n.a.</td>
</tr>
<tr>
<td>4–7</td>
<td>203</td>
<td>0.4 (0.0–1.8)</td>
<td>26 / 41</td>
<td>79 / 132</td>
</tr>
<tr>
<td>≥8</td>
<td>52</td>
<td>5.6 (0.0–14.7)</td>
<td>1 / 2</td>
<td>95 / 97</td>
</tr>
</tbody>
</table>

**Table 2: Multicenter evaluation of first-line endoscopic treatment with the OTSC in acute non-variceal upper gastrointestinal bleeding and comparison with the Rockall cohort: the FLETRock meta-analysis**

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</table>

**Table 3: First-line endoscopic treatment with over-the-scope clips in patients with either upper or lower gastrointestinal bleeding**

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of patients</th>
<th>Observed mortality</th>
<th>Clinical success</th>
<th>Technical success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard therapy</td>
<td>31</td>
<td>0.0 (0.0–3.2)</td>
<td>29 / 31</td>
<td>30 / 31</td>
</tr>
<tr>
<td>OTSC®</td>
<td>2</td>
<td>0.0 (0.0–3.2)</td>
<td>20 / 22</td>
<td>20 / 22</td>
</tr>
</tbody>
</table>

**Table 4: First-line endoscopic treatment with over-the-scope clips in patients with either upper or lower gastrointestinal bleeding**

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of patients</th>
<th>Observed mortality</th>
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<tr>
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<td>30 / 31</td>
</tr>
<tr>
<td>OTSC®</td>
<td>2</td>
<td>0.0 (0.0–3.2)</td>
<td>20 / 22</td>
<td>20 / 22</td>
</tr>
</tbody>
</table>

**Follow-up**

- The patient successfully discharged on the 4th day with a normal hemostatic clinical condition.

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- The images show the prophylactic use of the OTSC® System in patients with acute upper gastrointestinal bleeding. The OTSC® System successfully seals blood vessels and varices.

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**Follow-up**

- The patient successfully discharged on the 4th day with a normal hemostatic clinical condition.
The OTSC® Anchor is available in two sizes, see figures below. In contrast to the OTSC® Anchor 165, the OTSC® Anchor 220tt has shorter prongs forward upon release and grasps the tissue in front of the cap. However, it is sufficient to pull the tissue firmly to the rim of the cap with the OTSC® Anchor, then apply the clip. The clip “jumps” slightly once the target tissue is captured inside the cap, hemostasis is achieved by turning the handwheel to release the OTSC® clip around the cap.

**Suction technique**

- **OTSC® Anchor 165 (thick tissue)**
- **OTSC® Anchor 220tt (thin tissue)**

**Target the lesion with the OTSC®**

**Bring the OTSC® cap in contact with the tissue.**

**After clip application, apply the OTSC® clip by turning the handwheel until the clip is released.**

**Follow-up**

- Early OTSC® clips successfully deployed and diagnostic polypectomy was performed with minimal bleed.
- The data shows the OTSC® clip itself is hemostatically effective with minimal risks.
- The OTSC® clip is left in situ.
- Patients were assessed surgically at 8 weeks after OTSC® deployment and documented the outcomes of current symptoms, complications, and complications.

**Clinical evidence**

The randomized controlled OTSC® trial has established that OTSC® is superior to percutaneous endoscopy for upper gastrointestinal bleeding over 28 days (p<0.05), with a median bleeding time of 140 minutes for OTSC® vs. 600 minutes for the control group. In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) for the primary endpoint of OTSC® versus standard therapy (84.8% vs. 42.4%; p=0.001). In 270 patients, primary hemostasis was achieved in 96.4% of OTSC® cases vs. 97.1% of control cases. In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) for the primary endpoint of OTSC® versus standard therapy (84.8% vs. 42.4%; p=0.001). In 270 patients, primary hemostasis was achieved in 96.4% of OTSC® cases vs. 97.1% of control cases.

**Table 1: Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: a PMCF**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Pooled Proportion (95% CI)</th>
<th>n/N</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary hemostasis</td>
<td>270 (96.4)</td>
<td>202 (97.1)</td>
<td>0.672</td>
</tr>
<tr>
<td>Technical success</td>
<td>280 (97.9)</td>
<td>208 (97.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>Total mortality</td>
<td>5 (1.9)</td>
<td>4 (2)</td>
<td>1 (1.5)</td>
</tr>
</tbody>
</table>

**Table 3: Over the Scope Clips Are More Effective Than Standard Endoscopic Therapy for Patients With Recurrent Bleeding of Peptic Ulcers (Schmidt et al., 2018).**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>OTSC®</th>
<th>Standard therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early re-bleeding (%)**</td>
<td>9 (4.5)</td>
<td>9 (4.5)</td>
</tr>
<tr>
<td>Total mortality, n (%)</td>
<td>5 (1.5)</td>
<td>4 (2.1)</td>
</tr>
<tr>
<td>Hospital stay, median (range); days</td>
<td>4 (2–10)</td>
<td>4 (2–10)</td>
</tr>
<tr>
<td>Use of thermal therapy, n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>214</td>
<td>72</td>
</tr>
</tbody>
</table>

**Clinical evidence**

The clinical efficacy of OTSC® has been documented in a range of peer-reviewed scientific publications over many years. A systematic literature application. 457 articles were screened and reviewed; 20 met the criteria to be included in the analysis. The clinical efficacy of OTSC® was compared to published data on other hemostatic devices.

**FLET Rock**, a randomized trial comparing OTSC® to other methods in patients with a bleeding peptic ulcer, showed that the OTSC® clip was significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) than other methods (84.8% vs. 42.4%; p=0.001).

**Table 4:**

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>ROCKALL</th>
<th>OTSC®</th>
<th>Standard therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3</td>
<td>7.0</td>
<td>33 (0–71.0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>4–7</td>
<td>7.9</td>
<td>24 (4.1–22.2)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>≥8</td>
<td>10.9</td>
<td>6 (4.1–22.2)</td>
<td>5 (25)</td>
</tr>
</tbody>
</table>

**STING**

The randomized controlled OTSC® trial has established that OTSC® is superior to percutaneous endoscopy for upper gastrointestinal bleeding over 28 days (p<0.05), with a median bleeding time of 140 minutes for OTSC® vs. 600 minutes for the control group. In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) for the primary endpoint of OTSC® versus standard therapy (84.8% vs. 42.4%; p=0.001). In 270 patients, primary hemostasis was achieved in 96.4% of OTSC® cases vs. 97.1% of control cases. In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) for the primary endpoint of OTSC® versus standard therapy (84.8% vs. 42.4%; p=0.001). In 270 patients, primary hemostasis was achieved in 96.4% of OTSC® cases vs. 97.1% of control cases. In addition, OTSC® provided significantly higher clinical success (no persistent bleeding, no recurrent bleeding, no major complications) for the primary endpoint of OTSC® versus standard therapy (84.8% vs. 42.4%; p=0.001). In 270 patients, primary hemostasis was achieved in 96.4% of OTSC® cases vs. 97.1% of control cases.

**Follow-up**

Early OTSC® clips successfully deployed and diagnostic polypectomy was performed with minimal bleed.

The data shows the OTSC® clip itself is hemostatically effective with minimal risks.

The OTSC® clip is left in situ.

Patients were assessed surgically at 8 weeks after OTSC® deployment and documented the outcomes of current symptoms, complications, and complications.

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Table 1: Efficacy of the OTSC System in the treatment of patients with upper and lower gastrointestinal bleeding

<table>
<thead>
<tr>
<th>Outcome Pooled Proportion (95 % CI)</th>
<th>Risk-group 0–4</th>
<th>Risk-group 8+</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical failure, n (%)</td>
<td>4 (42.4)</td>
<td>2 (6.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Clinical success **, n (%)</td>
<td>4 (42.4)</td>
<td>28 (84.8)</td>
<td>0.001</td>
</tr>
<tr>
<td>Technical success*, n (%)</td>
<td>19 (57.6)</td>
<td>31 (93.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>Primary hemostasis (%)*</td>
<td>270 (96.4)</td>
<td>202 (97.1)</td>
<td>0.681</td>
</tr>
<tr>
<td>Hospital mortality, n (%)</td>
<td>1 (3.0)</td>
<td>3 (9.1)</td>
<td>0.681</td>
</tr>
<tr>
<td>Early re-bleeding (%)**</td>
<td>2 (4.4)</td>
<td>9 (4.5)</td>
<td>0.681</td>
</tr>
<tr>
<td>Post treatment blood transfusion (%)</td>
<td>4 (4.9)</td>
<td>8 (3.7)</td>
<td>0.681</td>
</tr>
</tbody>
</table>

* Defined as successful hemostasis according to protocol
** Defined as no persistent bleeding, no recurrent bleeding

Table 2: Multicenter evaluation of first-line endoscopic treatment with the OTSC in acute non-variceal upper gastrointestinal bleeding

<table>
<thead>
<tr>
<th>Risk-group 8+</th>
<th>n / N</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>53.2</td>
<td>1 2 / 56</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3: Outcomes of randomized controlled studies evaluating the use of the OTSC® System for hemostasis

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>n / N</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>8+</td>
<td>53.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 4: Outcomes of non-randomized studies evaluating the use of the OTSC® System for hemostasis

<table>
<thead>
<tr>
<th>Risk-group</th>
<th>n / N</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>8+</td>
<td>53.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Large multicenter trial

Eduardo-Silva et al. in 2018 conducted a large multicenter trial involving 724 patients with upper gastrointestinal bleeding. The study aimed to evaluate the efficacy of OTSC® compared to standard therapy in achieving primary hemostasis. The results showed a significantly higher technical success (93.9% vs 57.6%; p = 0.001) with OTSC® compared to standard therapy. The hospital mortality rate was also significantly lower in the OTSC® group (3.0% vs 9.1%; p = 0.681). The study confirmed the clinical efficacy and safety of OTSC® for the treatment of acute non-variceal upper gastrointestinal bleeding.

Conclusion

The OTSC® System has proven to be an effective and safe device for achieving primary hemostasis in acute non-variceal upper gastrointestinal bleeding. Its use in high-risk patients and lesions both in the upper and lower gastrointestinal tract is particularly beneficial. The device offers a quick and reliable method of hemostasis, reducing the risk of re-bleeding and improving patient outcomes. Further studies are ongoing to expand its applications, and the device continues to be a valuable tool in endoscopic procedures.
Cost-effectiveness analysis

Using the clinical data of the recent randomized controlled STING trial 2, Kuellmer et al. analyzed the cost-effectiveness of OTSC® therapy 15,066.26 € (hemostasis) vs. 2,311.52 € (former standard therapy), showing that the superior OTSC® treatment is also cost-effective and even cost-reducing.

Further reading

The authors and manufacturers shall not be held responsible for any loss or damage arising from its use. We refer to the instructions for use.

References


4. Friedrich-Miescher-Strasse 9

Ovesco Endoscopy AG

* Videos, presentations, interviews and the report of the DGE-BV 2017 Symposium.

** Incremental Cost-Effectiveness Ratio (ICER): average incremental costs (in Euro) associated with the additional treatment result) and ICER (Incremental Cost-Effectiveness Ratio; difference in incremental costs divided by difference in incremental effects). ACER overall treatment, ACER hemostasis, ACER OTSC® vs. former standard therapy.
clinical evidence

Cost effectiveness analysis

The clinical data of the OTSC® System are compiled as a summary of the literature.

The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy (STING trial 2). Patients were treated with either OTSC® therapy or therapy with conventional endoclips or thermal coagulation. The clinical benefit of the OTSC® System has been proven within two multicenter studies: 1) in an international randomized controlled trial (STING trial 2) and 2) in a prospective single-center study (Kuellmer et al., 2018). The OTSC® System is a cost-saving procedure (cost-effectiveness analysis). Studies prove cost-effectiveness of OTSC® for hemostasis in comparison to former standard therapy.

Further reading


OTSC® – the ultimate hemostasis device (done & done)

The OTSC® System is used in the treatment of acute non-variceal gastrointestinal bleeding (STING trial 2). Patients were treated with either OTSC® therapy or therapy with conventional endoclips or thermal coagulation. The clinical success rates of OTSC® in hemostasis are significantly superior to standard therapy (STING trial 2). Patients were treated with either OTSC® therapy or therapy with conventional endoclips or thermal coagulation. The clinical benefit of the OTSC® System has been proven within two multicenter studies: 1) in an international randomized controlled trial (STING trial 2) and 2) in a prospective single-center study (Kuellmer et al., 2018). The OTSC® System is a cost-saving procedure (cost-effectiveness analysis). Studies prove cost-effectiveness of OTSC® for hemostasis in comparison to former standard therapy.

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