



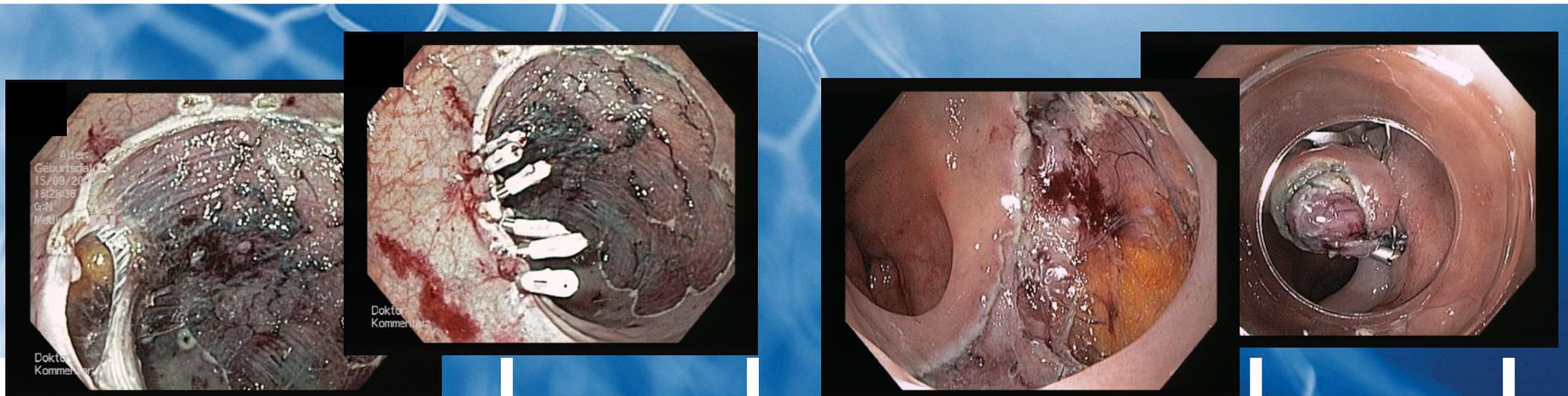
Iatrogene Perforationen

Wann Endoskopie?

9. Jahrestagung der Gesellschaft für Gastroenterologie
und Hepatologie in Berlin und Brandenburg. 24.1.2015

Karel Caca

Klinikum Ludwigsburg

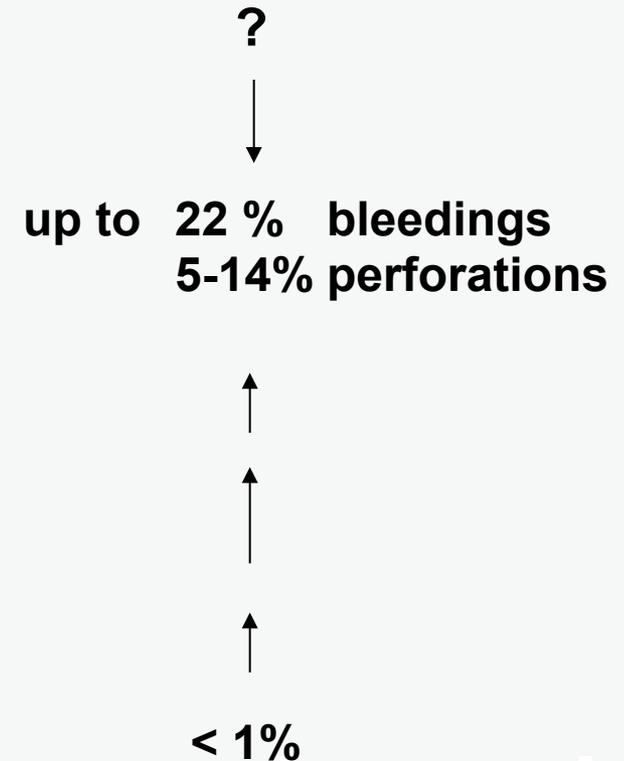
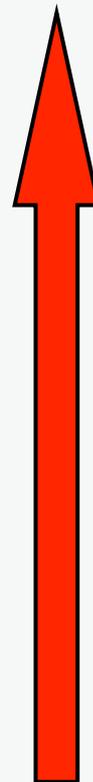
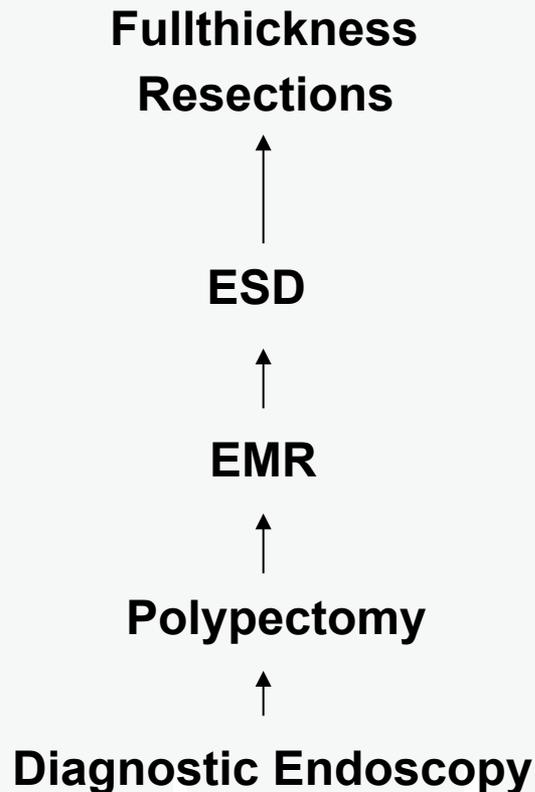




Interventionelle Endoskopie = Komplikationen ↑

Invasiveness

Complications





EMR / ESD Kolon - Komplikationen

| Range of lesion sizes (mm) | CER | | | ESD | | | CER Sub total | ESD | Total |
|---------------------------------|---------|---------|---------|---------|---------|----------|------------------|---------|---------|
| | 20-29 | 30-39 | ≥40 | 20-29 | 30-39 | ≥40 | | | |
| Lesion number | 729 | 194 | 106 | 219 | 258 | 339 | 1029 | 816 | 1,845 |
| Procedure time (min, mean ± SD) | 13 ± 13 | 43 ± 23 | 42 ± 46 | 66 ± 45 | 79 ± 42 | 129 ± 83 | 18 ± 23 | 96 ± 69 | 53 ± 63 |
| Complication | | | | | | | | | |
| Delayed bleeding | 12 | 4 | 2 | 3 | 7 | 8 | 18 | 18 | 36 |
| (%) | (1.6) | (2.1) | (1.9) | (1.4) | (2.7) | (2.4) | (1.7) | (2.2) | (2) |
| Perforation | 5 | 3 | 0 | 4 | 7 | 5 | 8 | 16 | 24 |
| (%) | (0.7) | (1.5) | (0) | (1.8) | (2.7) | (1.5) | (0.8) | (2.0) | (1.3) |
| Emergency surgical operation | – | 1 | – | – | – | 2 | 1 | 2 | 3 |
| (%) | | (0.5) | | | | (0.6) | (0.1) | (0.2) | (0.2) |
| En bloc resection rate | 485 | 88 | 13 | 206 | 248 | 317 | 586 | 771 | 1,357 |
| (%) | (66.5) | (45.4) | (12.3) | (94.1) | (96.1) | (93.5) | (56.9) | (94.5) | (73.6) |
| Non-curative resection | 33 | 9 | 2 | 23 | 24 | 31 | 44 | 77 | 122 |
| (%) | (4.5) | (4.6) | (1.9) | (10.5) | (9.3) | (9.1) | (4.3) | (9.4) | (6.6) |
| Additional surgery | 29 | 9 | 3 | 17 | 22 | 23 | 41 | 62 | 103 |
| (%) | (4.0) | (4.6) | (2.8) | (7.8) | (8.5) | (6.8) | (4.0) | (7.6) | (5.6) |

Kolonperforation - Chirurgie

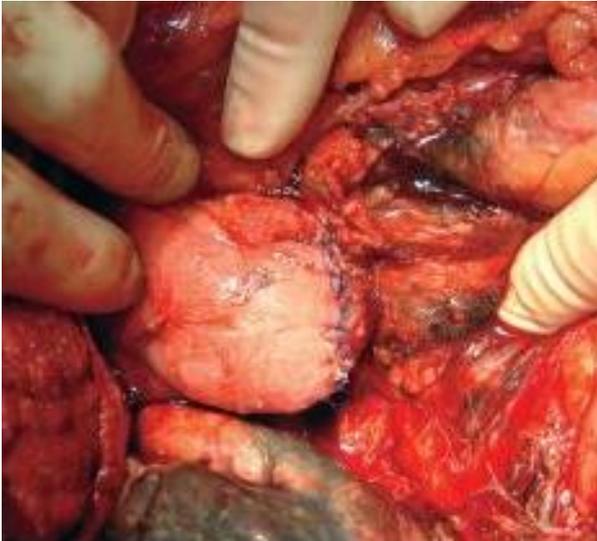


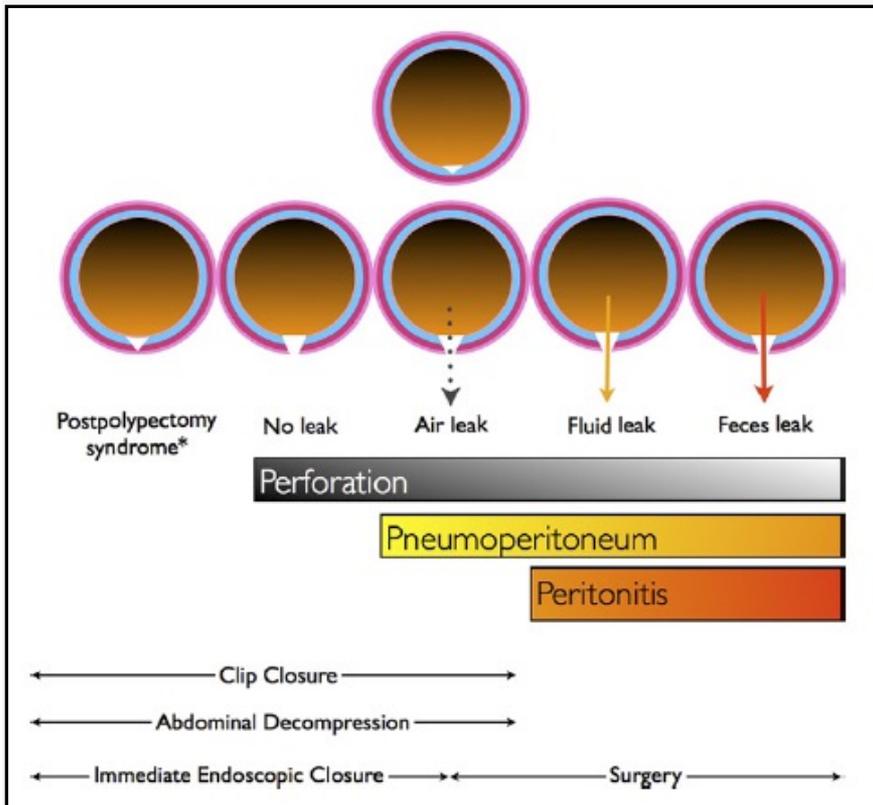
Table 4. Multiple Logistic Regression Analysis for Predictors of Mortality

| Factor | Relative Risk (95% CI) | P Value |
|----------------------------------|------------------------|-------------------|
| ASA class ≥ 3 | 11.73 (1.35-102.20) | .009 ^a |
| Antiplatelet therapy | 8.28 (1.26-54.71) | .001 ^a |
| Age >60 y | 1.43 (0.14-14.35) | .45 |
| Time to presentation >48 h | 0.32 (0.04-2.93) | .21 |
| Fair to poor bowel preparation | 3.25 (0.59-18.03) | .35 |
| Moderate to severe contamination | 12.67 (1.32-121.47) | .16 |

- Morbidität 39-63 %
- Mortalität 0-50 %
- Stomarate 38,5 %

Endoskopischer Perforationsverschluss

- Prinzipien -



10 + 1 Gebote

1. Sofortige Identifikation der Perforation
2. „Freie Luft“ \neq Chirurgie
3. Menge „freier Luft“
 \neq proportional zur Perforationsgröße
4. „Freie Luft“ \neq infektiös
5. „Freie Luft“ unter Spannung
= medizinischer Notfall
6. „Freie Luft“ disseziert = „Emphysem“
7. „Freie Luft“ kann persistieren
ohne klinische Konsequenz
8. Perforationen verschließen sich
in der Regel nach Drainage o. Diversion
9. Leckage von Kontrastmittel
→ unmittelbare Intervention erforderlich
10. Frustranter endoskopischer Verschluss
→ Chirurgie
11. Frühzeitige Antibiotikagabe



Endoskopische Verschlusstechniken im GI-Trakt

Clips

QuickClip2 (Olympus)

Resolution Clip (BS)

TriClip (Cook)

Instinct Clip (Cook)

Clipmaster (Medwork)

OTSC (Ovesco)



Nahtverfahren

T-Tags (Ethicon)

Purse string modified T-
Tags (Cook)

Eagle Claw VIII (Olympus)

Purse string-suturing
device (LSI)

EndoStitch (Apollo)

Flexible EndoStitch
(Covidien)

EndoCinch (Bard)

SurgAssist (Power Medical)

ESD (Cook)

G-Prox (USGI)

GERDX(G-Surg)

Esophyx (Endogastr. Sol.)

.....

Stents

Plastik

Metall

+/- Cover



„Schwämme“

E-VAC

ETVARD





Endoskopische Verschlusstechniken im GI-Trakt

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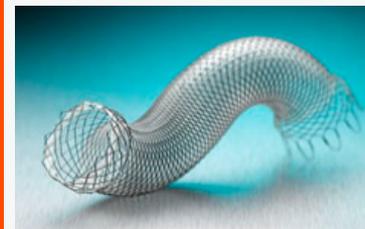
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Stents

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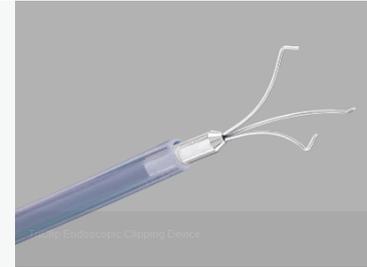
Through-The-Scope Clips



Olympus Quick Clip 2 (7.5 mm)
Olympus Quick Clip 2 Long (9 mm)



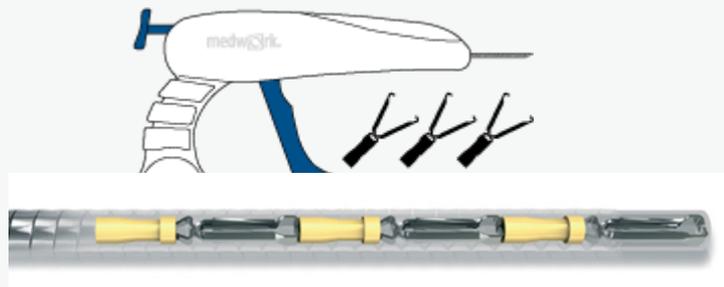
Olympus EZ Clip
(4, 6, 7.5, 9 mm; 90°+135°)



Cook TriClip



**Boston
Resolution Clip**



Medwork Clipmaster



Cook Instinct Clip

Perforationsverschluß - Through-The-Scope Clips

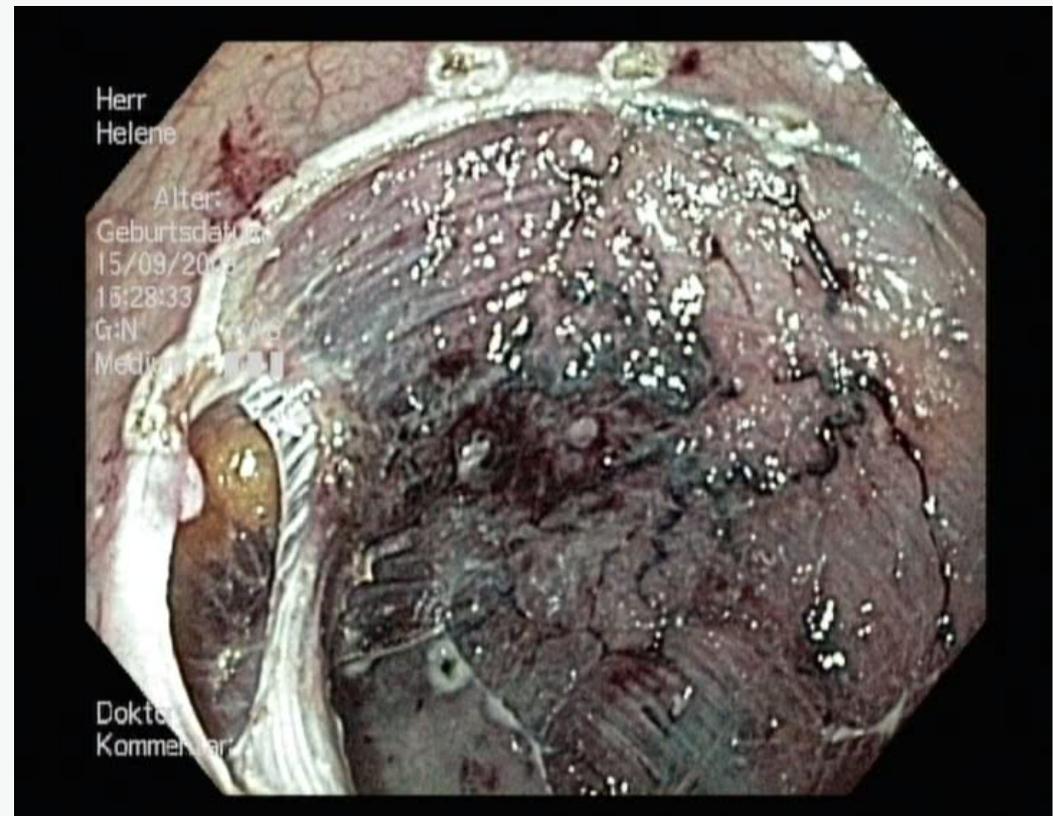
Technik:

**Linearer Verschluß –
(„Reißverschluß“)**

**Sichere Adaptation der
Perforationsränder unter Druck
essentiell**

Limitationen:

- **Größe der Perforation**
- **Form – „nahezu“ linear**
- **Lokalisation**
- **„Qualität“ der Ränder**



Perforationsverschluß Through-The-Scope Clips

Retrospektive Studie

7589 Koloskopien

30 Perforationen

-> 28/30 endoskop. Verschluß erfolgreich

-> 2/30 Chirurgie

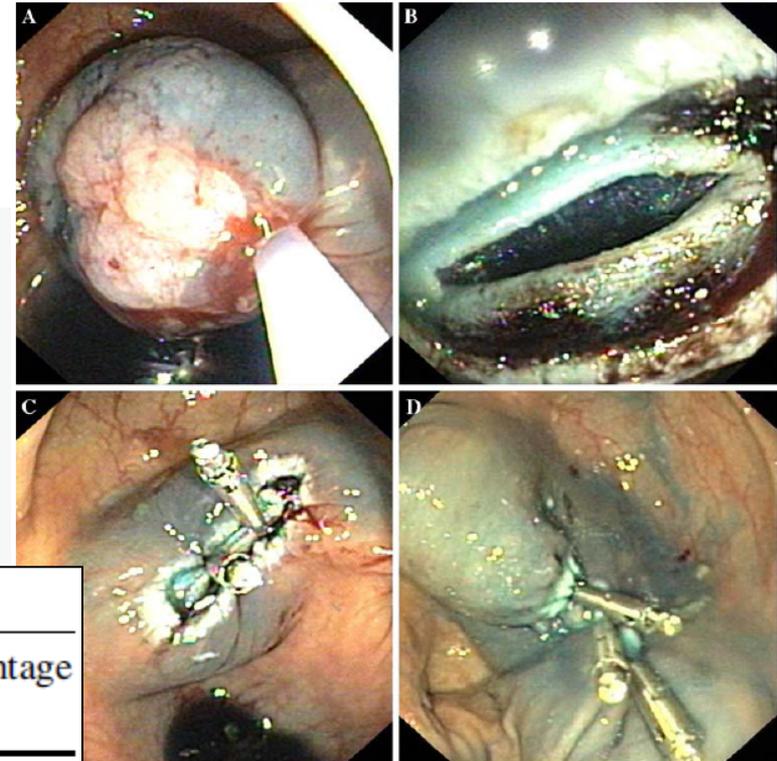
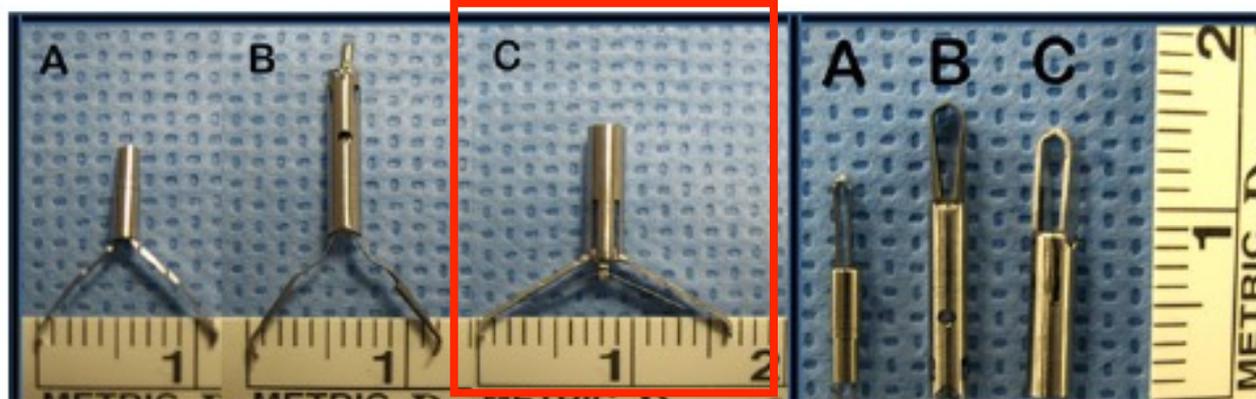


Table 4 Endoluminal repair of perforation with clips

| | Number of Patients | Percentage |
|---|--------------------|------------|
| Perforation recognized within endoscopy | 28/30 | 93.3% |
| Clip application not possible | 1/28 | 3.6% |
| Initial surgery | 1/1 | 100% |
| Clip application possible | 27/28 | 96.4% |
| Conservative treatment | 25/27 | 92.6% |
| Surgery after clip application | 2/27 | 7.4% |

Through-The-Scope Clips

QuickClip2, Resolution Clip, Instinct Clip



| | A | B | C |
|---|---------------------------|-------------------------------------|------------------------------|
| Features | QuickClip2 long (Olympus) | Resolution clip (Boston Scientific) | Instinct clip (Cook Medical) |
| Sheath diameter (French) | 7 | 7 | 7 |
| Sheath length (cm) | 235 | 230 | 230 |
| Jaw opening width (mm) | 11 | 11 | 16 |
| Inside measurements of the closed clip (mm) | 1.25 × 5.09 × 0.96 | 1.53 × 4.74 × 1.57 | 1.59 × 5.5 × 1.72 |
| Reopening and repositioning ability | No | Yes | Yes |
| Rotation ability | Yes | No | Yes |
| Clip material | Stainless steel | Stainless steel | Stainless steel and nitinol |
| Deployment | Two-step | Three-step | Two-step |
| MRI approval | No | No | Up to 3 tesla |



Through-The-Scope Clips

Biomechanic ex-vivo comparison

QuickClip2, Resolution Clip, Instinct Clip

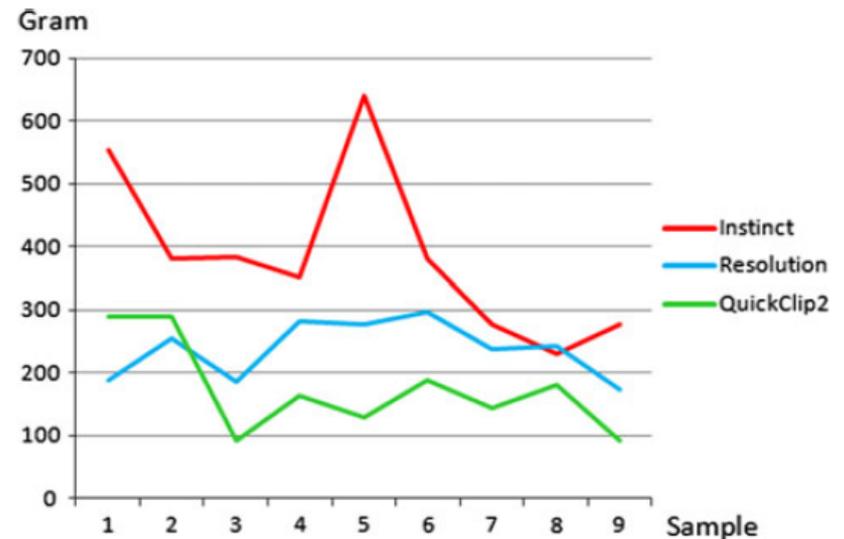
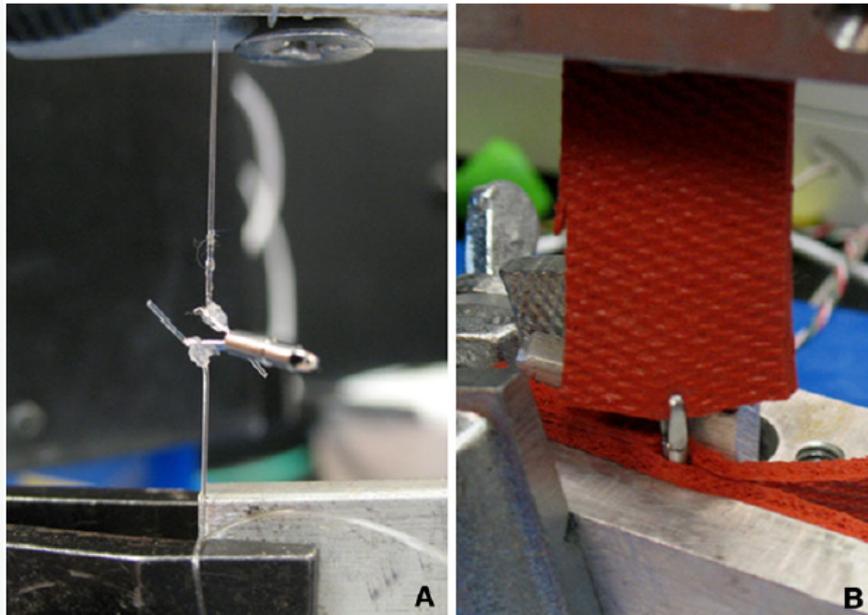
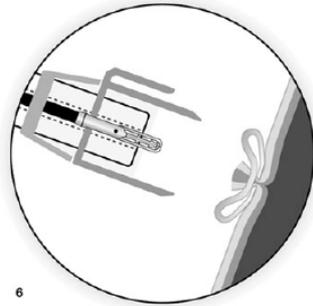
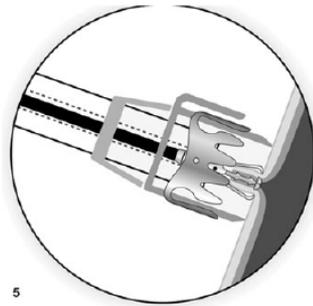
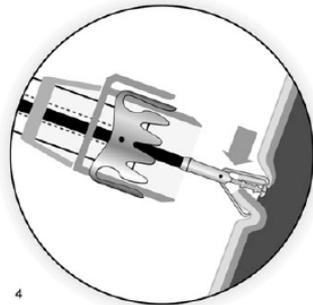
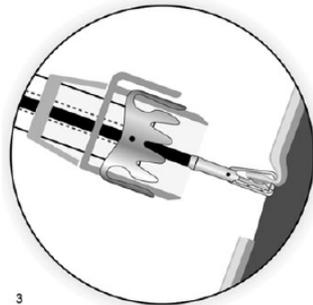
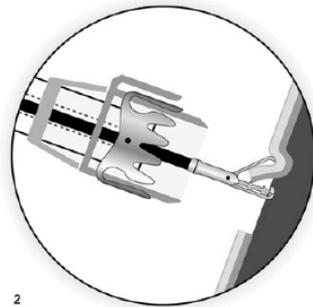
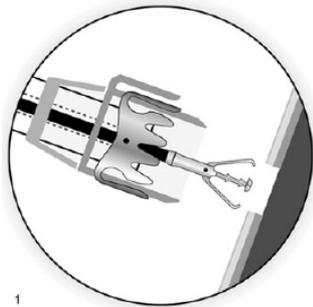
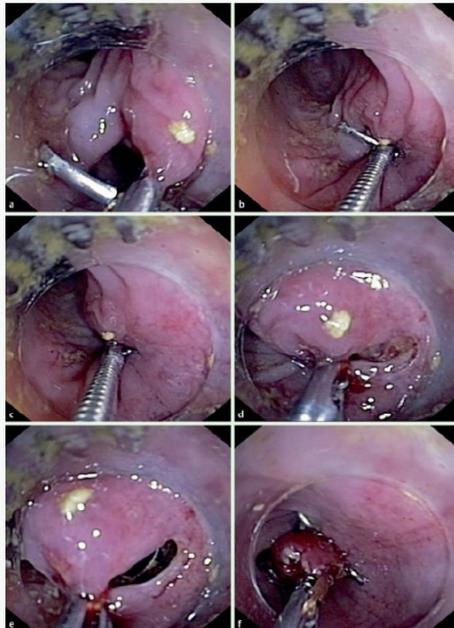


Fig. 8 Graph showing different opening strengths needed to open a closed clip

Over-The-Scope Clips (OTSC, Ovesco)



Perforationsverschluß – OTSC – animal in-vivo study



Randomized
in vivo animal study
Kolon Perforationen
(n=24)

Burst pressure

Kolon nativ: 140 mmHg

Perforationsverschluß – OTSC – animal in-vivo study



Randomized
in vivo animal study
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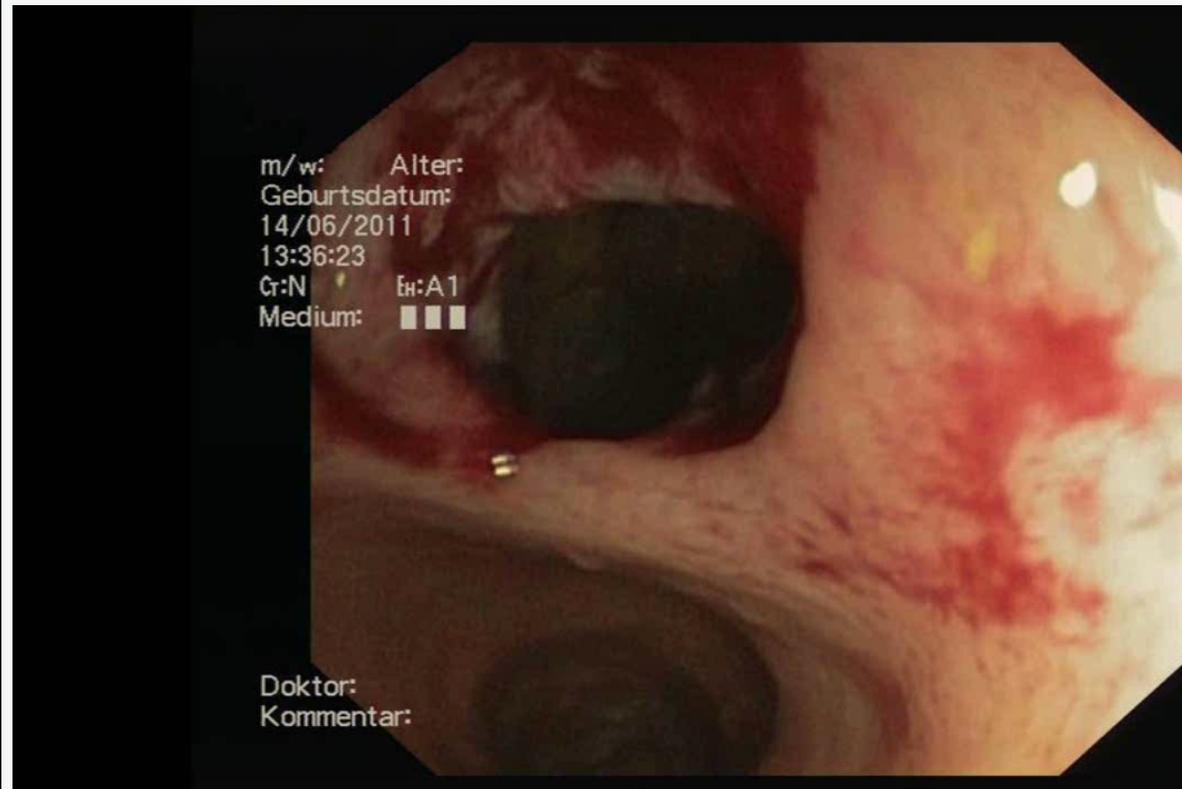
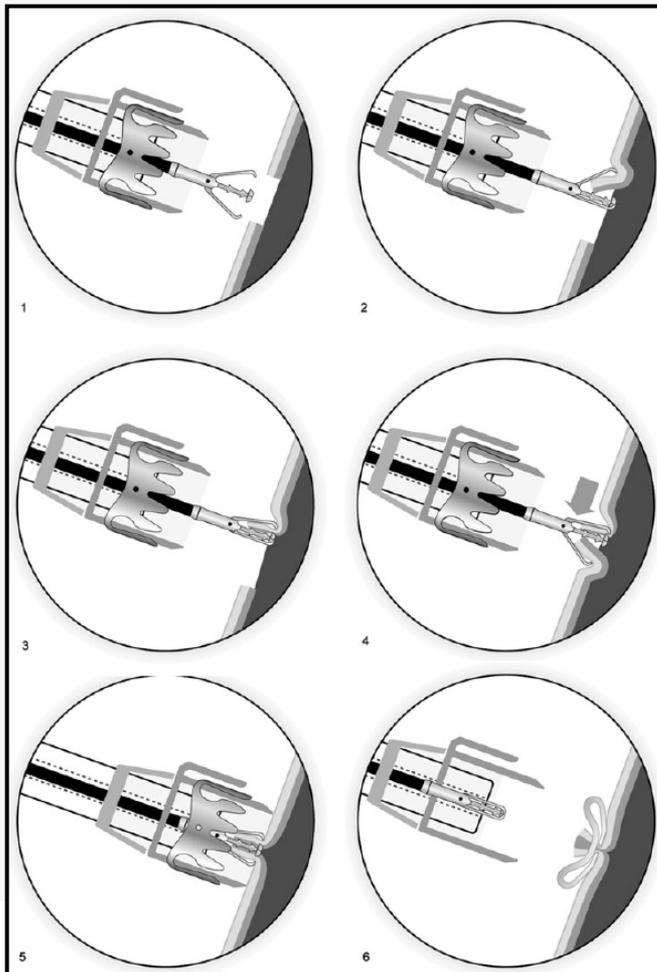
OTSC: 62,8 mmHg

Surgical sutures: 67,4 mmHg

(p=0,693)



Perforationsverschluß – Kolon - OTSC





Perforationsverschluß OTSC: Prospektive Multicenter-Studie

Design:

- Prospektiv, international, multi-zentrisch
- Primäre Endpunkte: erfolgreicher Verschluß, adverse events < 30d

Patienten:

- Akute iatrogene Perforationen (5x Oesoph.; 6x Magen; 12x Duodenum; 13 Kolon)

Ergebnisse:

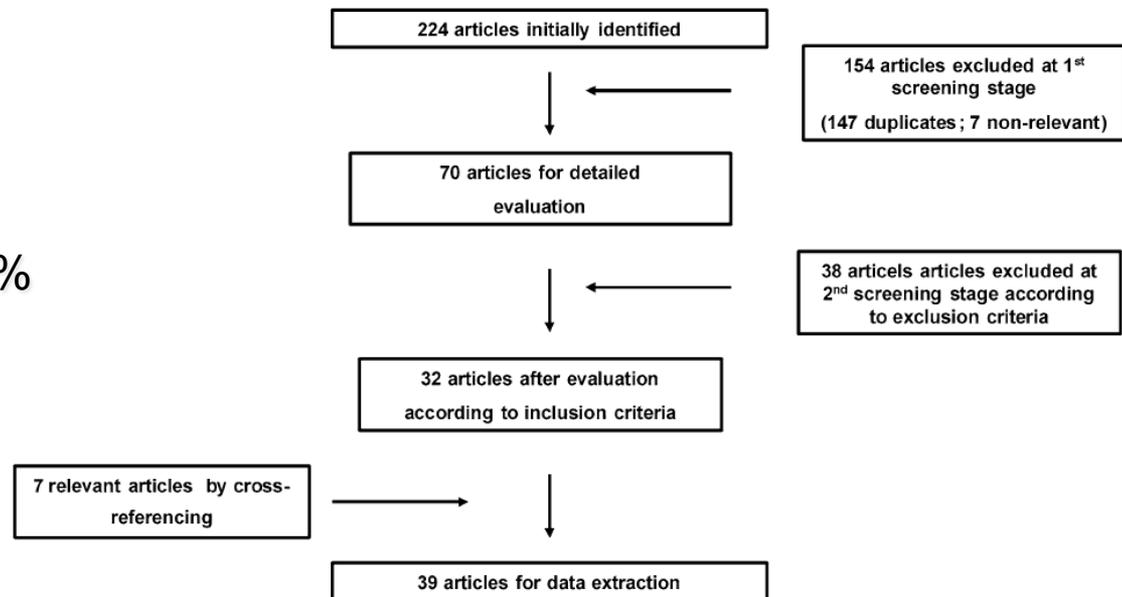
- **Erfolgreicher Verschluß: 92%**
- OP erforderlich: 3 Patienten
- 1 Todesfall innerhalb von 36 Stunden nach erfolgreichem Verschluß einer Kolonperforation
- **Gesamt-Erfolgsrate: 89%**
- Dauer des Eingriffs: 5 min

| Location | Total (n = 36) | Successful endoscopic closure (%) |
|-----------|-------------------|--------------------------------------|
| Esophagus | 5 (14) | 5 (100) |
| Stomach | 6 (17) | 6 (100) |
| Duodenum | 12 (33) | 9 (75) |
| Colon | 13 (36) | 12 (92) |



Perforationsverschluß OTSC: Metaanalyse

- 17 klinische Studien
- 22 präklinische Studien
- Technischer Erfolg 80-100%
- Klinischer Erfolg: 57-100%
- Keine SAE's
- Applikation schwierig bei
→ Vernarbung, Entzündung



DC Clip Cutter (Fa. OVESCO)

- Klinische Ergebnisse -



Table 1 Patient characteristics.

| Patients | |
|--------------------------|----|
| Total, n | 11 |
| Male, n | 7 |
| Female, n | |
| Age, mean (range) | |
| OTSC site | |
| Esophagus | |
| Gastric antrum | |
| Pylorus | |
| Pyloric-jejunal junction | |
| Descending colon | |
| Sigmoid colon | |
| Rectum | |
| Time OTSC in situ, days | |

Table 2 Indications for over-the-scope clip placement and removal.

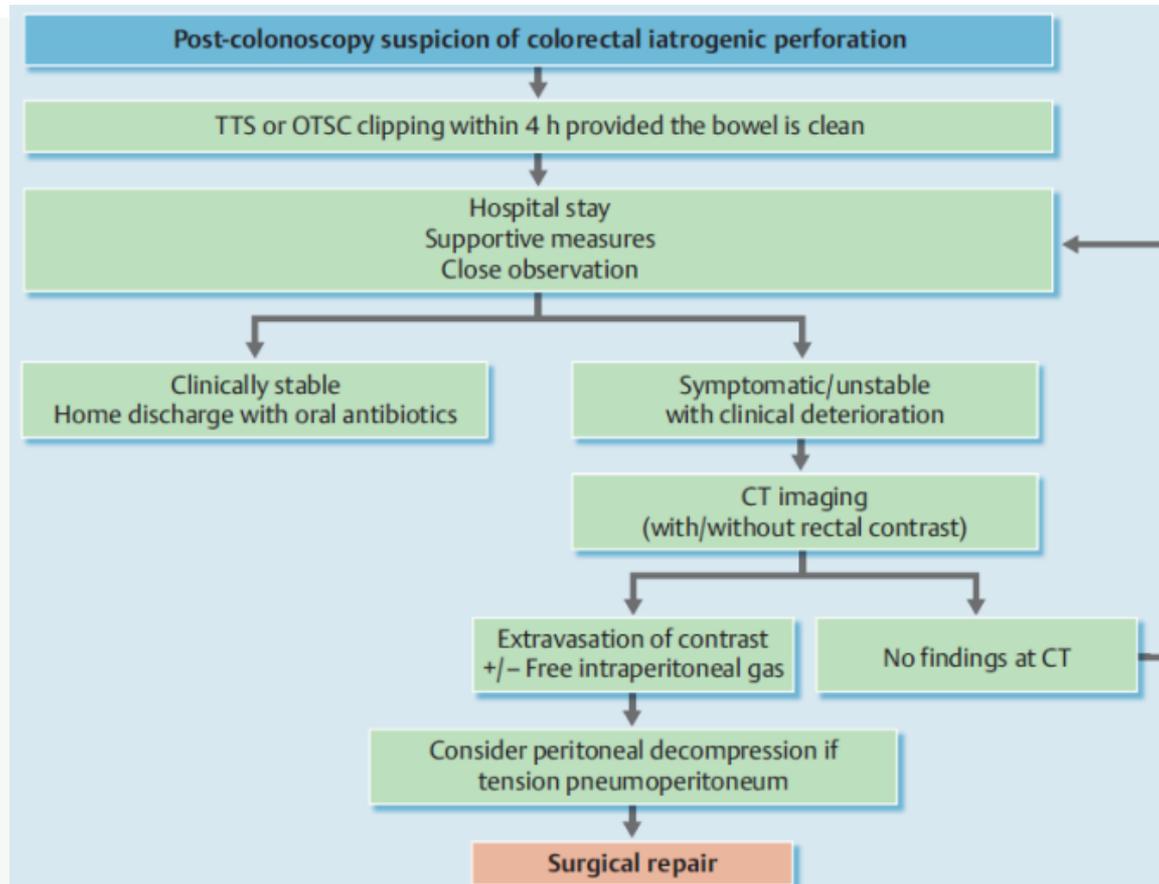
| Patient # | Indication for clip placement | Time clip in situ, days | Indication for clip removal |
|-----------|---|-------------------------|--|
| 1 | Closure of perforation after resection of a submucosal gastric mass | 31 | Intermittent epigastric pain attributed to a persistent gastric ulcer underneath the OTSC |
| 2 | Ulcer bleeding | 62 | Obstruction of the pylorus by the OTSC; intermittent epigastric pain, vomiting |
| 3 | Closure of duodenal perforation after resection of adenoma | 70 | Need for repeat biopsy at the resection site (duodenal bulb) to check for local recurrence of an adenoma |
| 4 | Closure of mucosal defect after resection of a gastric submucosal tumor | 70 | Intermittent abdominal pain, attributed to "foreign body" by the patient |
| 5 | Full-thickness resection of recurrent sigmoid adenoma | 208 | |
| 6 | Fixation of a migration esophageal stent | 74 | |
| 7 | Bleeding ulcer at a pyloric-jejunal anastomosis | 305 | |
| 8 | Closure of a rectal perforation after ESD of an adenoma | 465 | |
| 9 | Closure of mucosal defect in the esophagus after POEM | 54 | |
| 10 | Bleeding pyloric ulcer | 113 | |
| 11 | Bleeding ulcer at pre-pyloric antrum | 70 | |

Table 3 Success rates and complications.

| | n/N (%) |
|-----------------------------------|---------------|
| Procedure success | |
| Cutting of clip | 11 / 11 (100) |
| Removal of all clip fragments | 10 / 11 (91) |
| Overall success | 10 / 11 (91) |
| Adverse events | |
| Minor bleeding at OTSC site | 2 / 11 (18) |
| Major bleeding at OTSC site | 0 / 11 (0) |
| Perforation at OTSC site | 0 / 11 (0) |
| Mucosal tear with minor bleeding* | 1 / 11 (9) |

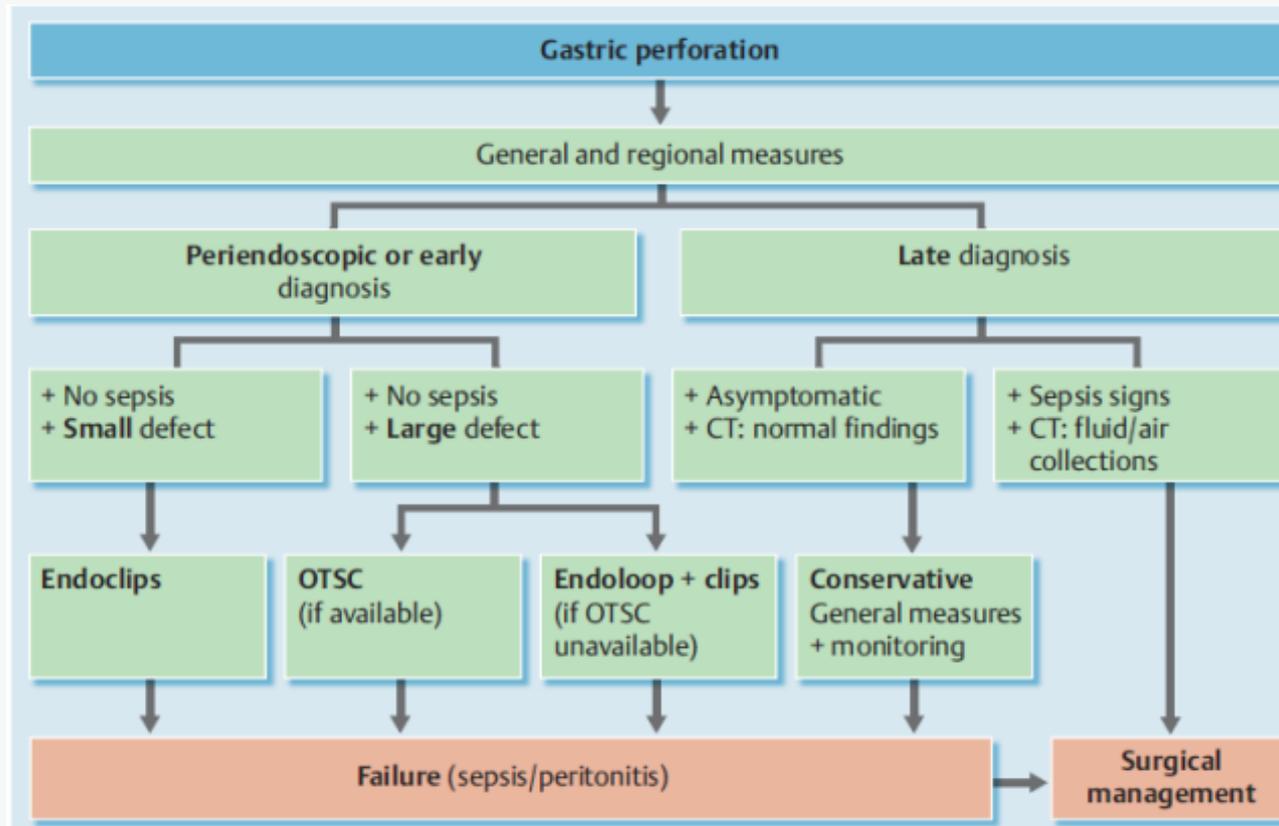


ESGE Positionspapier - Kolonperforation



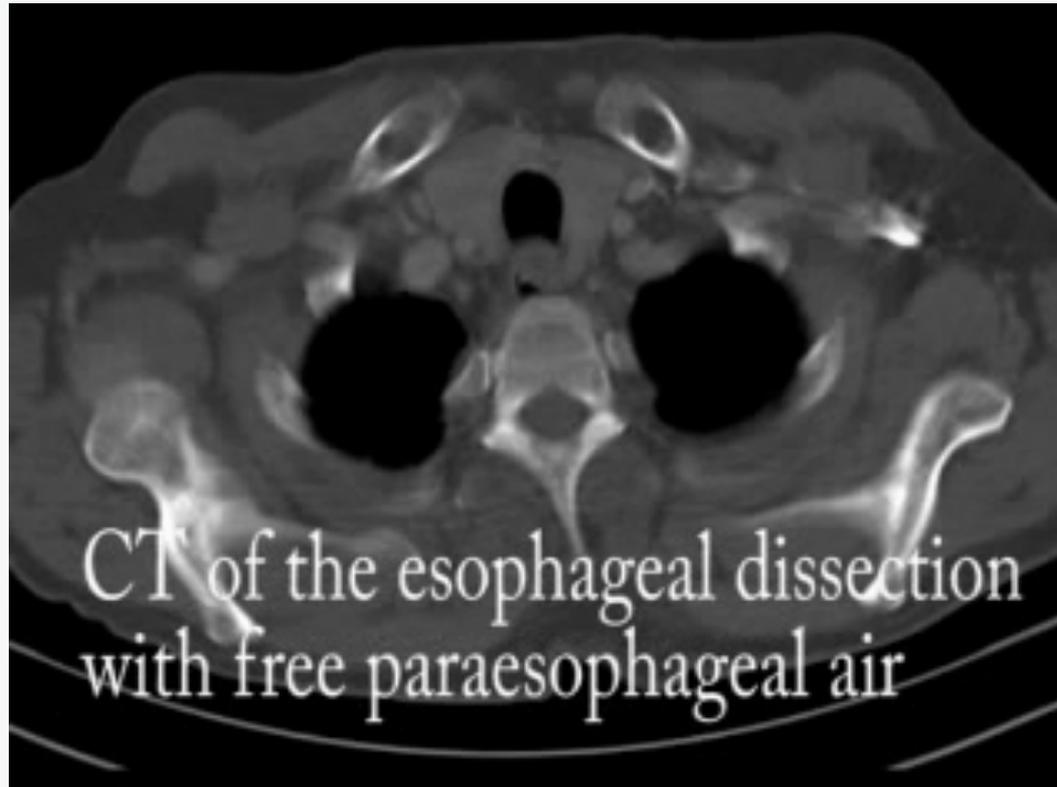


ESGE Positionspapier - Magenperforation





Ösophagusperforation - Endoskopische Stenttherapie





Ösophagusperforation - Chirurgie

| Treatment | Number of Patients | Number of Deaths | Mortality (%) Mean (Range) |
|-------------------------------|--------------------|------------------|-------------------------------|
| Primary repair | 322 | 40 | 12 (0–31) |
| Resection | 129 | 22 | 17 (0–43) |
| Drainage | 88 | 32 | 36 (0–47) |
| Exclusion and Nonoperative | 33 | 8 | 24 (0–80) |
| Total | 726 | 128 | 18 (0–80) |



Ösophagusperforation – Endoskopische Therapie

- **Stents**
- Primär endoskopischer Verschuß
 - **Clips**, endoskopische Naht
- Endoskopische Transmurale Drainage
 - nasomediastinale Drainage
 - transmurale Stents
 - **E-VAC (Vakuumsystem)**



Ösophagusperforation

Endoskopische Therapie - Stents

| Authors | Number of patients | Mortality rate (%) |
|---|--------------------|--------------------|
| Kiev <i>et al.</i> [9] | 14 | 0 |
| Freeman <i>et al.</i> [10] | 17 | 0 |
| Kim <i>et al.</i> [11] | 16 | 6 |
| Salminen <i>et al.</i> [12 [•]] | 32 | 16 |
| Leers <i>et al.</i> [13 [•]] | 31 | 6 |



Iatrogene Perforation – Endoskopische Therapie

Zusammenfassung

- **Primat der endoskopischen Therapie**
- **Verschlusstechnik abhängig von Anatomie**
- **Clipverschluß = Standardtechnik**
- **Stenttherapie etablierte Standardtherapie im Ösophagus**
- **Zeitfaktor! Antibiose und Verschluß!**
- **Drainage (endoskopisch/perkutan) bei verzögertem Verschluß**