

# OTSC<sup>®</sup> Proctology Over-The-Scope Clipping System for colorectal surgery

## OVERVIEW



### Over-The-Scope Clipping System for colorectal surgery

#### PRINCIPLE

OTSC Proctology is an innovative clipping system for the treatment of wall defects in the anorectum (e.g. fistulas). Dynamic closure of the inner orifice with the super-elastic nitinol clip represents the basic principle of this therapy. The procedure is low in complications and side effects and minimizes the risk of incontinence by preserving the sphincter. The stapler-like and intuitive design of the transanal clip applicator enables a quick and easy use.

#### SUMMARY OF CLINICAL DATA

The literature describes OTSC Proctology as a safe and effective device. A median operation time of about 30 minutes confirms the feasibility of the procedure and the short learning curve of the method. No exceptional postoperative pain was experienced by the patients and no incontinence was reported. Published literature reports of healing rates of 70.89%\* (95% CI, 49.99 to 87.97%; p=0.0622) in first-line treatment and 64.10%\* (95% CI, 55.85 to 71.96%; p=0.8215) overall success (incl. recurrences). The authors evaluate OTSC Proctology as an effective, safe and simple procedure for the treatment of anal fistula.

*\*calculated from a pooled proportional analysis based on the studies by Mennigen et al (2015), Probst/Joos (2016) and Dango et al. (2017). The pooled proportion analysis provides a more accurate estimate of the sum of the different studies with different participants.*

#### PRACTICAL CONCLUSION:

OTSC Proctology combines sphincter preservation with high clinical effectiveness

Treatment with OTSC Proctology is a new method for complex anal fistulas, which shows high success rates, especially in first-line therapy. It is characterized by:

- Safety: sphincter-preserving procedure
- Effectiveness: high fistula healing rates
- Minimally invasive surgical technique and simple handling
- Procedure low in complications.

## OTSC® Proctology Over-The-Scope Clipping System for colorectal surgery

### Overview of literature

#### The anal fistula claw: the OTSC clip for anal fistula closure.

R.L. Prosst\*, A. Herold\*\*, A.K. Joos\*\*, D. Bussen\*\*, M. Wehrmann°, T. Gottwald°, M.O. Schurr§°, \*Proctological Institute Stuttgart, \*\*End- und Dickdarm-Zentrum Mannheim, °Pathological Institute Nuertingen, °°Ovesco AG Tuebingen, §Steinbeis University Berlin, IHCI-Institute Tuebingen. 2012  
Colorectal Dis. 2012 Sep;14(9):1112-7. doi: 10.1111/j.1463-1318.2011.02902.x.

#### The OTSC® Proctology clip system for anal fistula closure: First prospective clinical data

R.L. Prosst\*, W. Ehni\*, A.K. Joos\*\*, \*Proctological Institute Stuttgart und \*\*End- und Dickdarm-Zentrum Mannheim, 2013  
Minim Invasive Ther Allied Technol. 2013 Sep;22(5):255-9. doi: 10.3109/13645706.2013.826675. Epub 2013 Aug 25.

#### Anorektaler Fistelverschluss mit dem OTSC Proctology

R.L. Prosst\*, A.K. Joos\*\*, W. Ehni\*, D. Bussen\*\*, A. Herold\*\*, \*Proktologisches Institut Stuttgart, \*\*End- und Dickdarm-Zentrum Mannheim, 2014  
CHAZ 15. Jahrgang 1. Heft 2014.

#### Prospective pilot study of anorectal fistula closure with the OTSC Proctology

R.L. Prosst\*, A.K. Joos\*\*, W. Ehni\*, D. Bussen\*\*, A. Herold\*\*, \*Proctological Institute Stuttgart und \*\*End- und Dickdarm-Zentrum Mannheim, 2015  
Colorectal Dis. 2015 Jan;17(1):81-6. doi: 10.1111/codi.12762.

#### The OTSC® proctology clip system for the closure of refractory anal fistulas

R. Mennigen, M. Laukötter, N. Senninger, E. Rijcken, University Hospital Muenster, 2015  
Tech Coloproctol. 2015 Apr;19(4):241-6. doi: 10.1007/s10151-015-1284-7. Epub 2015 Feb 26.

#### Easy clip to treat anal fistula tracts: a word of caution.

M. Gautier\*, P. Godeberge, R. Ganansia, G. Bozio, B. Godart, M.A. Bigard, M. Barthet, L. Siproudhis, \*CHU Pontchaillou, Rennes, France, Groupe de Recherche en Proctologie SNFCP France, 2015  
Int J Colorectal Dis. 2015 May;30(5):621-4. doi: 10.1007/s00384-015-2146-5. Epub 2015 Feb 13.

#### Comment on: Easy clip to treat anal fistula tracts: a word of caution by M. Gautier et al.

M.O. Schurr\*, R.L. Prosst\*\*, \*IHCI Steinbeis University Berlin, \*\*Proctological Institute Stuttgart, 2016  
Int J Colorectal Dis. 2016 Mar;31(3):707-8. doi: 10.1007/s00384-015-2197-7. Epub 2015 Apr 17.

#### Therapeutic management of complex anal fistulas by installing a nitinol closure clip: study protocol of a multicentric randomised controlled trial—FISCLOSE

A. Dubois<sup>1</sup>, G. Carrier<sup>1</sup>, B. Pereira<sup>2</sup>, B. Gillet<sup>1</sup>, J.-L. Faucheron<sup>3</sup>, D. Pezet<sup>1,2,4,5</sup>, D. Balayssac<sup>2,5,6</sup>. <sup>1</sup>CHU Clermont-Ferrand, service de Chirurgie Digestive, Clermont-Ferrand, France, <sup>2</sup>CHU Clermont-Ferrand, Délégation à la Recherche Clinique et à l'Innovation, Clermont-Ferrand, France, <sup>3</sup>CHU Grenoble, service de Chirurgie Digestive, Grenoble, France, <sup>4</sup>INSERM, U1071, Clermont-Ferrand, France, <sup>5</sup>Université d'Auvergne, Clermont-Ferrand, France, <sup>6</sup>INSERM, U1107 NEURO-DOL, Clermont-Ferrand, France  
BMJ Open 2015;5:e009884 doi:10.1136/bmjopen-2015-009884.

#### Short-term outcomes of a novel endoscopic clipping device for closure of the internal opening in 100 anorectal fistulas

R.L. Prosst\*, A.K. Joos\*\*, \*Proctological Institute Stuttgart, \*\*End- und Dickdarm-Zentrum Mannheim, 2016  
Tech Coloproctol (2016): doi:10.1007/s10151-016-1537-0.

#### Long-term efficacy and safety of a nitinol closure clip system for anal fistula treatment

S. Dango\* \*\*, F. Antonakis\*, D. Schrader\*, A. Radzikhovskiy\*, M.B. Ghadimi\*\*, R. Hesterberg\*, \*Red Cross Hospital Kassel, \*\*University Medical Center Göttingen, 2017  
Minim Invasive Ther Allied Technol 2017 Aug; 26(4):227-231. doi: 10.1080/13645706.2017.1282521. Epub 2017 Feb 2.

#### Short-term efficacy and safety of three novel sphincter-sparing techniques for anal fistulae: systematic review

S.O. Adegbola\* \*\*, K. Sahnan\* \*\*, G. Pellino\*, P.J. Tozer\* \*\*, A. Hart\* \*\*, R.K.S. Phillips\* \*\*, J. Warusavitarne\* \*\*, O.D. Faiz\* \*\*, \*Fistula Research Unit, St. Mark's Hospital and Academic Institute, Harrow, UK, \*\*Department of Surgery and Cancer, Imperial College, London, UK, 2017  
Tech Coloproctol (2017): 21:775-782. doi: 10.1007/s10151-017-1699-4. Epub 2017 Oct 29.

# OTSC<sup>®</sup> Proctology Over-The-Scope Clipping System for colorectal surgery

## SUMMARY CLINICAL DATA

### The OTSC<sup>®</sup> Proctology clip system for anal fistula closure: First prospective clinical data

R.L. Prosst\*, W. Ehni\*, A.K. Joos\*\*, \*Proctological Institute Stuttgart and \*\*End- und Dickdarm-Zentrum Mannheim, 2013 [Minim Invasive Ther Allied Technol.](#) 2013 Sep;22(5):255-9. doi: 10.3109/13645706.2013.826675. Epub 2013 Aug 25.

- 10 patients (7 male, 3 female)
- median age: 55 years (25-73)
- 9 transsphincteric fistulas, 1 suprasphincteric fistula
- median operation time: 30 minutes (20-45)
- no intraoperative technical or surgical complications
- **90% healing rate** (follow-up 6 months): 4 patients with clip still in situ, 5 patients with clip detachment (10 days – 4 weeks)
- 1 patient with persistent fistula due to spontaneous clip detachment 3 days after surgery

### Prospective pilot study of anorectal fistula closure with the OTSC Proctology

R.L. Prosst\*, A.K. Joos\*\*, W. Ehni\*, D. Bussen\*\*, A. Herold\*\*, \*Proctological Institute Stuttgart and \*\*End- und Dickdarm-Zentrum Mannheim, 2015; [Colorectal Dis.](#) 2015 Jan;17(1):81-6. doi: 10.1111/codi.12762.

- 20 patients (14 male, 6 female) (10/2011 - 4/2013)
- median operation time: 32 minutes (17-66)
- no intraoperative complications
- **90% healing rate** (18/20):
  - 13 patients with clip in situ (6 months follow-up)
  - 3 patients with spontaneous clip detachment (10 days - 4 weeks)
  - In 2 patients clip manually removed (1 clip displacement, 1 wound healing disorder)
- 10% persistence (2/20): 1 early clip detachment 3 days after procedure, 1 persistent fistula secretion
- no fecal incontinence suffered

#### Conclusion:

- minimally invasive technique
- procedurally simple and time-efficient
- associated with high patient satisfaction

### The OTSC procedure and its (ill) successes in the clinical routine

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

J. Al-Haidary, D. Zieker, T. Borschitz, J. Rimpel, L. Duschka, Wiesbaden; Presented at 41st Conference of Coloproctologists, Munich, 2015

- 44 patients (30 male, 14 female)
- median age: 47 years (24-72)
- 25 transsphincteric fistulas, 3 intrasphincteric fistulas, 2 suprasphincteric fistulas, 4 rectovaginal fistulas, 8 anal fistulas, 1 recto-vesical fistula, 1 pouch fistula
- operation time: 16-95 minutes
- **78% healing rate in first line**
- **42% healing rate in recurrence**
- **64% healing rate** in patients with Crohn's disease

#### Conclusion:

- only little preparation of fistula needed & positive learning curve
- special forms of fistulas can be treated (recto vaginal and pouch fistula)

## OTSC<sup>®</sup> Proctology Over-The-Scope Clipping System for colorectal surgery

### The OTSC<sup>®</sup> proctology clip system for the closure of refractory anal fistulas

R. Mennigen, M. Laukötter, N. Senninger, E. Rijcken, University Hospital Muenster, 2015

[Tech Coloproctol](#). 2015 Apr;19(4):241-6. doi: 10.1007/s10151-015-1284-7. Epub 2015 Feb 26.

- 10 patients (5 male, 5 female) (10/2012 - 6/2014)
- median age: 41 years (26-29)
- 4 cryptoglandular fistulas, 6 perianal Crohn's disease (1 patient with anovaginal fistula)
- technically successful in all patients
- only refractory cases
- median follow-up: 230.5 days (156-523 days)
- **70% healing rate** (7/10): median time 72 days (31-109)
- 30% persistence (3/10) due to spontaneous clip detachment on days 22, 23, 40 (2 cryptoglandular fistulas, 1 Crohn's disease-associated fistula)
- clip removal in 3/7 patients with successful closure

#### Conclusion:

- safe and effective method for the closure of even complex and recurrent fistulas

### Short-term outcomes of a novel endoscopic clipping device for closure of the internal opening in 100 anorectal fistulas

R.L. Prosst\*, A.K. Joos\*\*, \*Proctological Institute Stuttgart, \*\*End- und Dickdarm-Zentrum Mannheim, 2016

[Tech Coloproctol](#) (2016). doi:10.1007/s10151-016-1537-0.

- 100 procedures, 96 patients (64 male, 32 female)
- mean age: 50 years (20-80)
- 55 transsphincteric, 38 suprasphincteric, 2 extrasphincteric, 5 rectovaginal fistulas
- all but 11 fistulas (8 Crohn's, 3 ulcerative colitis) of cryptoglandular origin
- median operation time: 32 minutes (17-66)
- no intraoperative technical problems
- **79% healing rate in first line**
- **26% healing rate in recurrent fistulas**
- **65% overall healing rate**

#### Conclusion:

- OTSC Proctology provides convincing results as first-line treatment for complex cryptoglandular fistulas
- safe, effective, minimally invasive, and sphincter-sparing procedure
- postoperative pain comparable to other types of fistula surgery

### Long-term efficacy and safety of a nitinol closure clip system for anal fistula treatment

S. Dango\*\*\*, F. Antonakis\*, D. Schrader\*, A. Radzikhovskiy\*, M.B. Ghadimi\*\*, R. Hesterberg\*, \*Red Cross Hospital Kassel, \*\*University Medical Center Göttingen, 2017

[Minim Invasive Ther Allied Technol](#) 2017 Aug; 26(4):227-231. doi: 10.1080/13645706.2017.1282521. Epub 2017 Feb 2.

- 22 patients (19 male, 3 female)
- median age: 53 years (24-80)
- 21 patients with primary event, 1 recurrence (20 transsphincteric fistulas, 1 intrasphincteric fistula, 1 ano-vaginal fistula)
- no intra- or perioperative complications (technical success 100%)
- full preservation of continence in all patients, no postoperative pain
- Follow-up:  $\bar{x}$  36 months (13-42 months; year 1 after 1,3,6,9,12 months, year 2+3 every six months)
- Clip removal in all patients with complete healing after  $\bar{x}$  5,8 months (3-12 months)
- **59% healing rate (13/22) in first line**
- 41% recurrence (9/22) after  $\bar{x}$  6,9 months (3-11 months)
  - n=8 re-operated: definitive healing 22% (5/8)

#### Conclusion:

- effective and safe sphincter-preserving technique
- recommendable option for first line treatment of anal fistulas