Società Medico Chirurgica di Ferrara


REMDICONTO
DELLE ADUNANZE
dell' Accademia
MEDICO-CHIRURGICA
DI FERRARA
DEGLI ANNI
1846 – 1847 – 1848 – 1849

Innovazione e Trattamenti Mini Invasivi in Proctologia

Sabato 22 Settembre 2012
Aula Magna Nuovo Arcispedale S.Anna
Cona, Ferrara

Il Segretario
Dr. V. Giancarlo Matarese

Il Presidente
Dr. Sergio Gullini

Sono stati richiesti crediti formativi ECM per Medici, Biologi, Farmacisti, Infermieri
Sono disponibili attestati di partecipazione per gli studenti in Medicina
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Trattamento chirurgico della malattia perianale di Crohn

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Perianal Crohn's Disease

"PERIANAL DISEASE" FREQUENCY OF PROCTECTOMY

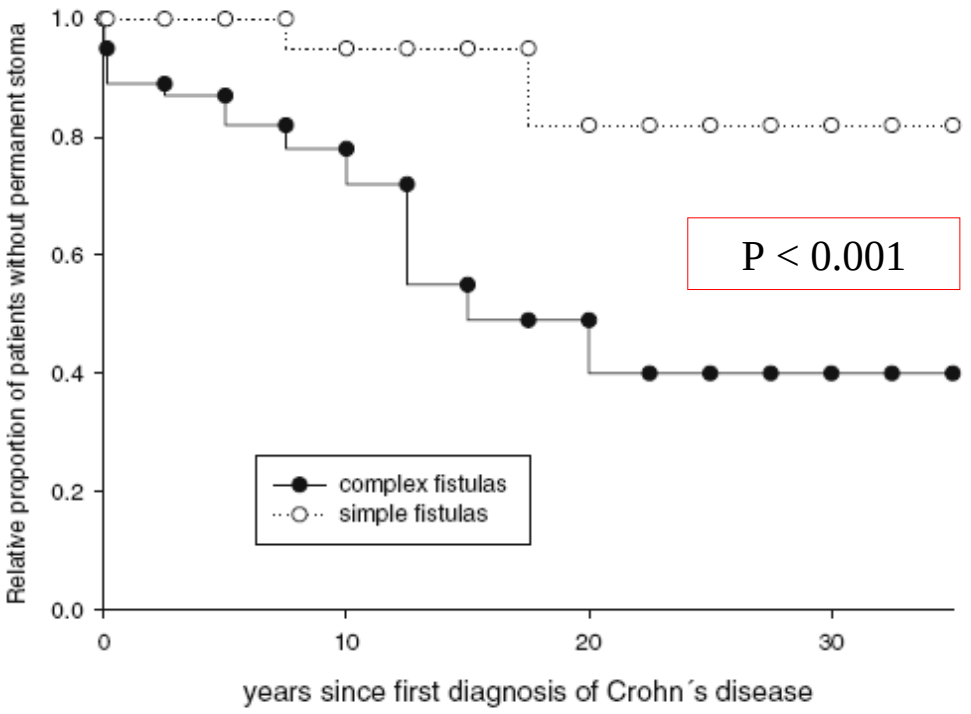
AGA Technical Review on Perianal Crohn's Disease | **GASTROENTEROLOGY, 2003**

Study	No. of patients	Treatment	Healed (%)	Recurrence (%)	Incontinence (%)	Proctectomy (%)
van Dongen et al.[20]	2	Seton	2 (100)	0	Not stated	0
Williams et al.[173]	22	Seton	19/22 (86)	9/19 (47)	14 (66)	3 (14)
Sangwan et al.[178]	24	Seton	22/24 (92)	17/24 (63)	Not stated	7 (33)
Scott et al.[176]	27	Seton	23/27 (85)	4/27 (15)	4 (15)	4 (15)
White et al.[164]	10	Seton	10/10 (100) improved 0 closed	2/10 (20) 0	Not stated	0
Koganei et al.[172]	13	Seton	10/13 (77) improved 8 (62) closed	3/10 (30) 0	0	1 (8)
Sugita et al.[181]	21	Seton	17/21 (81) improved 8 (38) closed	9/17 (53) 0	1 (5)	Not stated
Williams et al.[182]	23	Seton	20/23 (87) improved 3/23 (13) closed	9/20 (45) 0	6 (26)	5 (22)
Faucheron et al.[183]	41	Seton	36/41 (88) improved 11/41 (27) closed	8/36 (22)	5 (12)	5 (12)
Pearl et al.[184]	21	Seton	21/21 (100)	0	0	0
Williamson et al.[170]	9	Seton	7/9 (78)	2/9 (22)	Not stated	Not stated
McKee et al.[177]	7	Seton	4/7 (57)	3/7 (43)	Not stated	2 (29)
Halme et al.[175]	5	Seton or excision + fecal diversion	1 (20)	Not stated	Not stated	3 (60)
Morrison et al.[152]	2	Seton + lay open	2/2 (100)	Not stated	Not stated	0
Morrison et al.[152]	2	Lay open	2/2 (100)	Not stated	Not stated	0
McKee et al.[177]	5	Lay open	2/5 (40)	3/5 (60)	2 (40)	2 (40)
Halme et al.[175]	1	Lay open	0	0	Not stated	0
Nordgren et al.[21]	10	Lay open	4/10 (40)	1/4 (25)	Not stated	6 (60)
Morrison et al.[152]	2	Lay open and/or excision + fecal diversion	1/2 (50)	Not stated	Not stated	1 (50)
Matos et al.[185]	10	Excision and primary closure	10/10 (100)	6 (60)	5/10 (50)	0
Jones et al.[186]	6	Transanal full-thickness advancement flap	2/6 (33)	4/6 (67)	Not stated	1 (17)
Fry et al.[187]	3	Transanal advancement flap	3/3 (100)	0	Not stated	0
Lewis et al.[187]	6	Transanal full-thickness advancement flap	5/6 (83)	1/6 (17)	Not stated	0
Makowiec et al.[188]	20	Transanal advancement flap	16/20 (80)	4/20 (20)	0	0
Joo et al.[189]	26	Transanal advancement flap	19/26 (73)	7/26 (27)	Not stated	2 (9)
Robertson et al.[190]	6	Transanal advancement flap	3/6 (50)	3/6 (50)	Not stated	0
Williamson et al.[170]	4	Transanal advancement flap	1/4 (25)	3/4 (75)	Not stated	Not stated
McKee et al.[177]	2	Transanal advancement flap	1/2 (50)	1/2 (50)	Not stated	1 (50)
Marchesa et al.[191]	13	Sleeve advancement flap	8/13 (62)	5/13 (38)	Not stated	3 (23)

Risk of Fecal Diversion in Complicated Perianal Crohn's Disease

M. H. Mueller • M. Geis • J. Glatzle • M. Kasparek • T. Meile • E. C. Jehle • M. E. Kreis • T. T. Zittel

J Gastrointest Surg, 2007

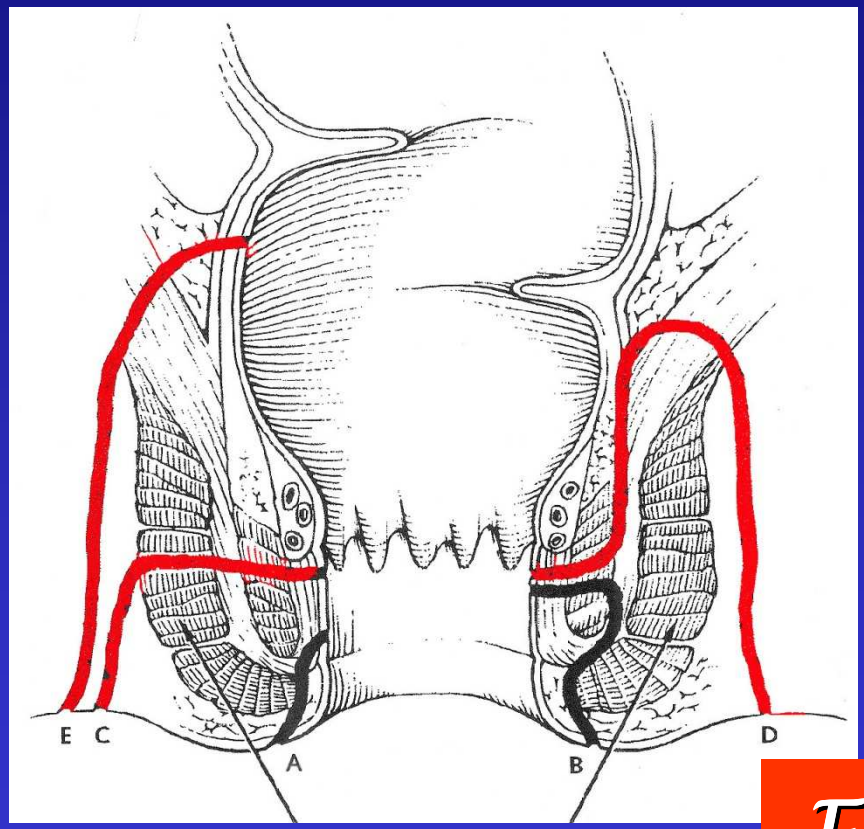


Risk Factors	Univariate Analysis		Multivariate Analysis		
	Permanent Fecal Diversion (%)	*P* Value	OR	95% CI	*P* Value
Rectal resection	92	*P*<0.001	30	5–179	*P*<0.002
Fecal incontinence	83	*P*<0.001	21	3–165	*P*<0.02
Subtotal colectomy	60	*P*<0.001			
Rectovaginal fistulas	54	*P*<0.001			
Temporary fecal diversion	51	*p*=0.001	8	2–35	*P*<0.02
Complex perianal fistulas	54	*P*<0.04	5	2–18	*P*<0.03

"…. complex perianal Crohn's disease, colo-rectal involvement, and a high rate of abdominal procedures carried a significant risk for a permanent stoma."

Perianal Sepsis and Fistula

GUIDELINES



Suprasphincteric extrasphincteric, trans-sphincteric

- **Drain the sepsis**
- **Try to identify fistulous tracts**

FINAL GOAL IS TO AVOID / DELAY OOSTOMY

THERAPY OF PERIANAL CROHN'S DISEASE

- Surgery
- **Biological drugs**
- Surgery + biological drugs
- Surgery + biological drugs + biological prothesis
- Etc …

Apparent wide availability of therapeutic options but…
which is the *CORRECT THERAPEUTIC ALGORITHM* ?

Treatment of Perianal Crohn's Disease

WHAT WE HAVE NOW

✓ Biological Drugs

- **Systemic**
- **Local injection**

Perianal Sepsis and Fistula

GUIDELINES

ECCO Statement 9J
Antibiotics and azathioprine/mercaptopurine should be used as the first choice of therapy for complex perianal Crohn's disease in combination with surgical therapy, in spite of a lack of clinical trials [EL4, RG D].
ECCO Statement 9K
Infliximab [EL1b, RGA] or adalimumab [EL1b, RGB] should be used as a second line medical treatment [EL1b, RGB].

ECCO

Statement 6D

Complex fistulas

IG-IBD the Italian Group for the study of Inflammatory Bowel Disease

Anti-TNFs should be used as the first choice of medical therapy for complex perianal Crohn's disease [Infliximab **EL1b, RG A**; Adalimumab **EL1b, RG B].** Combination with surgical therapy is recommended despite a lack of clinical trials **[EL4, RG D]**

Antibiotics and/or azathioprine/6-mercaptopurine should be used as a second line medical treatment, despite a lack of clinical trials **[EL4 RG D]**

INFLIXIMAB FOR THE TREATMENT OF FISTULAS IN PATIENTS WITH CD

D. Present et al (New England J Med, 1999: 340; 1398-405)

94 pts (*abdominal and perianal fistulas*)

Achieve the primary end-point of the trial

5 mg/Kg ⇒ 68 %; 10 mg / Kg ⇒ 56 %; Placebo ⇒ 26 %

NO SURGICAL APPROACH

Primary end-point efficacy: reduction of 50% or more in the number of draining fistulas

" The primary end-point was based on the Investigators' physical evaluation …. A fistula was considered closed when it no longer drained **DESPITE GENTLE FINGER COMPRESSION"** !

What happened in the last decade?

TREATMENT OF COMPLEX PERIANAL FISTULAS WITH SURGERY AND SISTEMIC BIOLOGICAL DRUGS

AUTHORS	STUDY DESIGN	METHOD	RESULTS	P
Topstad et al. *Dis Colon Rectum 2003*	Uncontrolled study on 29 pts (perianal and R-V fistulas) with Surgery and IFX	Surgery+IFX 0 wk-2wk-6wk every 8wk	PERIANAL FISTULA Healing 67% Partial healing 19% R-V FISTULAS Healing 13% Partial healing 62%	
Talbot et al. *Colorectal Dis 2005*	Uncontrolled study on 21 pts with Surgery and IFX	Surgery+IFX 0 wk-2wk-6wk	Healing 47% Partial healing 53%	
Sciaudone et al. *Can J Surg 2009*	Controlled study on 35 pts with IFX, Surgery or IFX+Surgery	IFX 0 wk-2wk–6wk-every 8wk Surgery 0 wk Surgery+IFX 0 wk-2wk-6wk-every 8wk	IFX Healing 63% Surgery Healing 70% Surgery+IFX Healing 78%	n.s.
Hotokezaka et al. *Hepatogastroenterology 2011*	Uncontrolled study on 20 pts; induction and maintenance with IFX	Surgical drainage 0 wk IFX infusion 2wk-4wk-8wk every 8wk	After induction Healing 40% Partial response 45% Maintenance Healing 75%	

Fistulating Anal Crohn's Disease: Results of Combined Surgical and Infliximab Treatment

Syed A. Hyder, F.R.C.S.,[1] Simon P. L. Travis, F.R.C.P.,[2] Derek P. Jewell, F.R.C.P.,[2]
Neil J. McC. Mortensen, F.R.C.S.,[1] Bruce D. George, F.R.C.S.,[1]

DCR, 2006

22 pts →

- **14** proctocolitis
- **3** segmental colitis
- **2** ileocecal and proctocolitis
- **3** ileocecal disease

DESIGN OF THE STUDY →

EUA (21/22) for drainage of sepsis → Infliximab infusion (5 mg/Kg) **within 24 hours of surgery** then 2 weeks and 6 weeks later.

RESULTS

Short Term: IMPROVEMENT 77 % PDAI

Long Term:

- **4/22 (18%)** : healing of the fistula
- **8/22 (27.3%):** reinsertion of seton
- **5/22 (22.7%):** defunctioning stoma / proctectomy
- **4/22 (18%):** Repeated infusion to maintain satisfactory symptom control

Long-term efficacy of infliximab maintenance therapy for perianal Crohn's disease

Motoi Uchino, Hiroki Ikeuchi, Toshihiro Bando, Hiroki Matsuoka, Yoshio Takesue, Yoshiko Takahashi, Takayuki Matsumoto, Naohiro Tomita

Department of Lower Gastroenterological Surgery, Hyogo College of Medicine, Japan

World J of Gastroenterology 2011

62 pts with perianal Crohn's disease

36 surgery alone *vs* 26 surgery + IFX

SURGERY0 vs SURGERY+IFX2wk-4wk-8wk–every 8wk

Short term efficacy (at12-15 wk)

- **COMPLETE HEALING**
  Not seen in both groups p = n.s.
- **FAILURE**
  27,8% no-IFX vs 15,4% IFX p = n.s.
- **PARTIAL IMPROVEMENT**
  72,2% no-IFX 88,5% IFX p = n.s.
- **DECREASE of mPDAI**
  13.5 to 9.5 no-IFX vs 11 to 6 IFX p < 0.01

Long term efficacy

- **RECURRENCE**
  More recurrence in no-IFX Group p = n.s.
  Highter recurrence in pts with anorectal stricture in both groups p = n.s.

"Long term benefit with infliximab was not proven"

Fistulating Anal Crohn's Disease: Results of Combined Surgical and Infliximab Treatment

DCR, 2006

Syed A. Hyder, F.R.C.S.,[1] Simon P. L. Travis, F.R.C.P.,[2] Derek P. Jewell, F.R.C.P.,[2] Neil J. McC. Mortensen, F.R.C.S.,[1] Bruce D. George, F.R.C.S.,[1]

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Department of Lower Gastroenterological Surgery, Hyogo College of Medicine, Japan

World J of Gastroenterology 2011

Possible BIAS of these studies:

- **Based on PDAI and mPDAI with *"clinical feeling"***
- **Not homogeneous surgical technique**
- **Confusion on seton removal and IFX use**

Infliximab and surgical treatment of complex anal Crohn's disease

S Duff, PM Sagar, M Rao, S Dolling, M Sprakes, P J Hamlin
Colorectal Unit and Department of Gastroenterology, The General Infirmary Leeds
United Kingdom

Colorectal Dis 2011

Evaluate the efficacy and duration of response to infliximab in the long-term management of perianal Crohn's disease

52 pts with complex fistulas treated with:

- **Preoperative antibiotics**
- **SURGICAL DRAINAGE AND SETON PLACEMENT**
- **Infliximab sistemic therapy**

Complete response defined as complete closure of the fistula with no further drainage on gentle finger pressure

!

RESULTS

42,3% complete response
44,2% partial response
13,5% no response

RECURRENCE

41% of pts complete responders
65% of pts partial responders
57% of pts no responders

P=0.005

"The response rate of Crohn's related complex perianal fistulae to infliximab are good. Complete response is associated with a reduction in need for surgical intervention"

1999

Infliximab for the treatment of fistulas in patients with Crohn's disease

Presentet al. ***New Eng J Med 1999***

2011

Infliximab and surgical treatment of complex anal Crohn's disease

S Duff et al. ***Colorectal Dis 2011***

After 12 yrs more relevance to SURGICAL PROCEDURES

BUT

TOO MUCH CONFUSION ABOUT THE *FINAL ISSUE*

Treatment of perianal Crohn's disease with combined surgical and i.v. biological therapy

Surgical Unit and Medical IBD Unit Bologna, 2012

95 pts with complex or simple fistula

fistula + rectal involvement

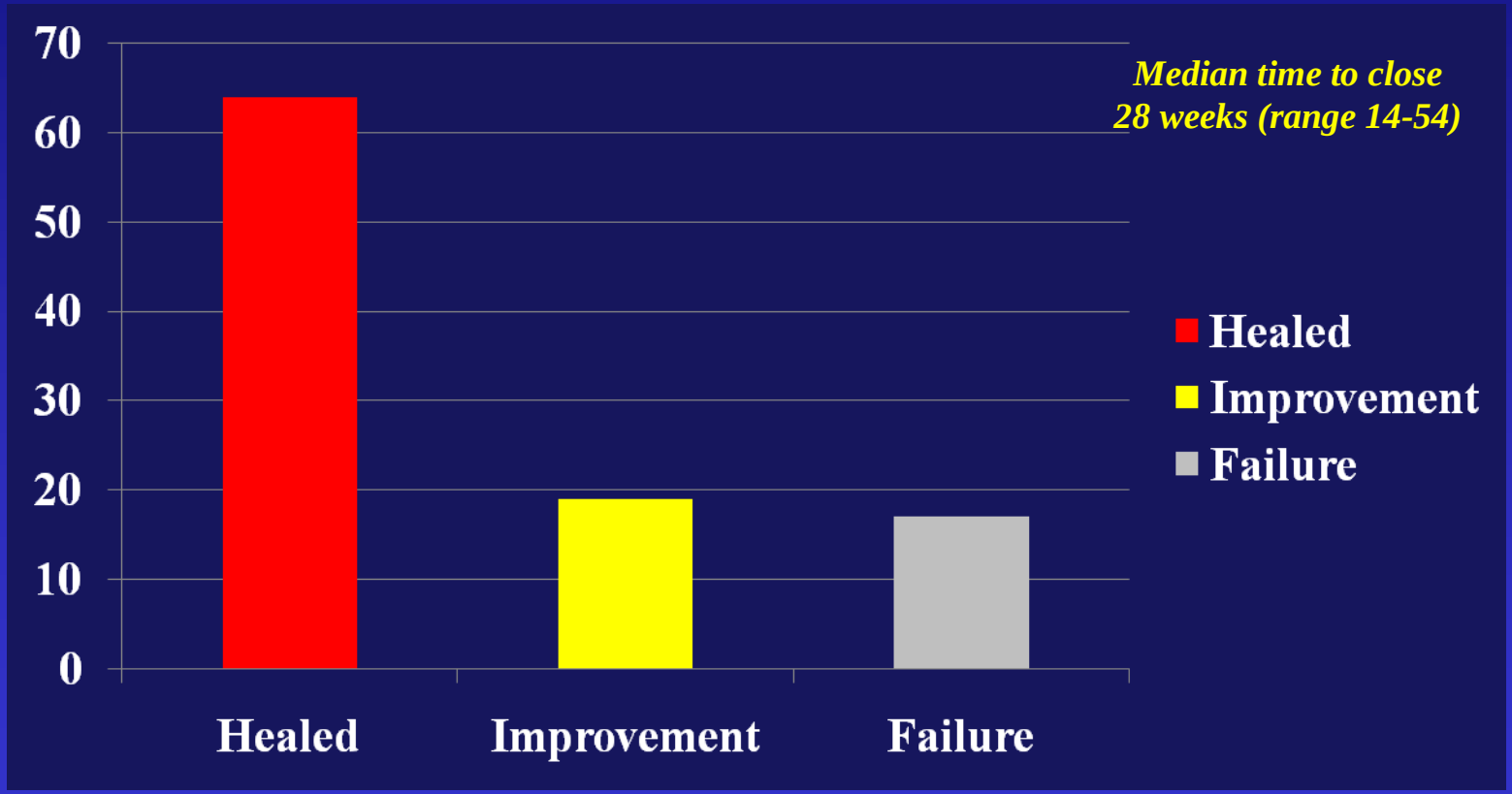
EUA and seton placement

Treated with i.v. IFX

(0,2,6 and every 8 weeks until fistula closure)

Treatment of perianal Crohn's disease with combined surgical and i.v. biological therapy

Surgical Unit and Medical IBD Unit Bologna, 2012



Healing : complete closure of fistulas tract (confirmed by EUA and MRI)
Improvement : reduction of drainage

Perianal Crohn's Disease

TREATMENT OF FISTULAS

FISTULECTOMY

"cone-like" technique

Perianal Crohn's Disease

TREATMENT OF COMPLEX FISTULAS

SANITIZING THE PERINEUM

"cone-like" technique

Perianal Crohn's Disease

TREATMENT OF COMPLEX FISTULAS

"MALIGNANT" PERIANAL DISEASE

Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB

Evaluation of effectiveness

Personal Score System

Grade 1: **Unmodified / Worsened**

Grade 2: **Sepsis control but persisting pus discharge from fistulas**

Grade 3: **No pus discharge; no granulation tissue**

Grade 4: **Closure with scar tissue (tested with probe examination)**

Perianal Crohn's Disease

TREATMENT OF COMPLEX FISTULAS

"MALIGNANT" PERIANAL DISEASE

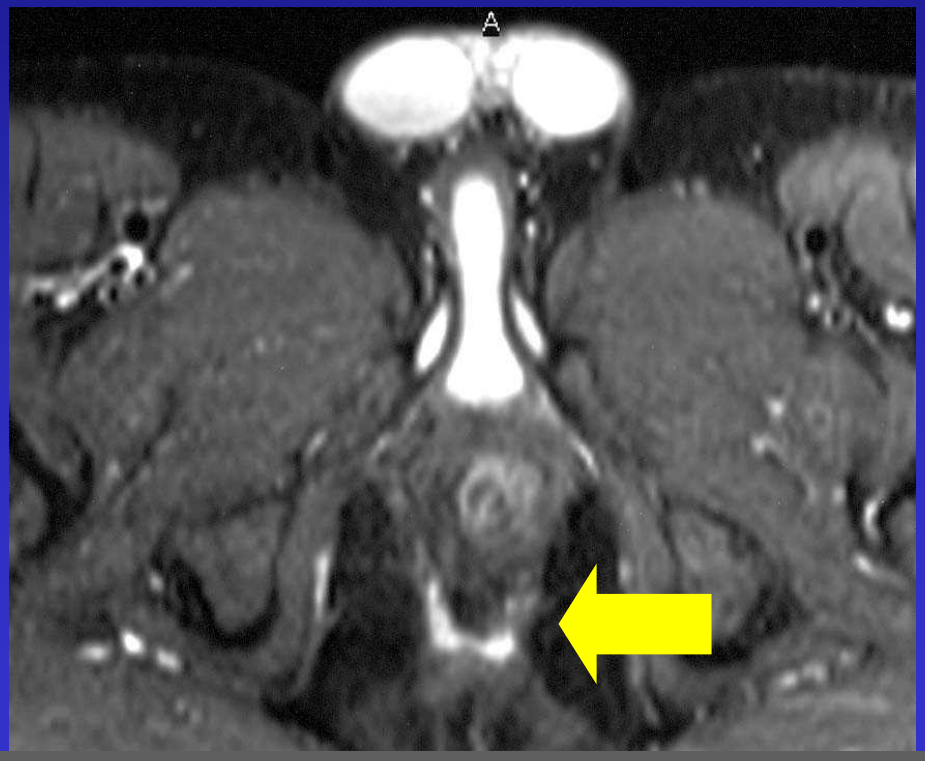
CONTROVERSIES

Perianal Crohn's Disease

The Role of MRI in assessing Fistula Healing

FALSE CLOSURE

Before infliximab



3 months after infliximab

INFLIXIMAB FOR PERIANAL FISTULAS

*There is a place for treating perianal fistulas with **local injection** of Infliximab ?*

RATIONALE

- Patients not suitable for I.V. Infliximab ***(stenosis!)***
- High dose in the fistula tract
- Lower cost → 20 mg/pt instead of 5-10 mg /Kg

Diseases of the COLON & RECTUM
OFFICIAL JOURNAL OF THE AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS

Local Injection of Infliximab for the treatment of perianal Crohn's Disease

*G. Poggioli, M.D., S. Laureti, M.D., F. Pierangeli, M.D., F. Rizzello *, MD, F. Ugolini, M.D, P. Gionchetti *, MD, M. Campieri *, MD*

General Surgery Department; Policlinico S. Orsola; University of Bologna, Italy

** Internal Medicine Department; Policlinico S. Orsola; University of Bologna, Italy*

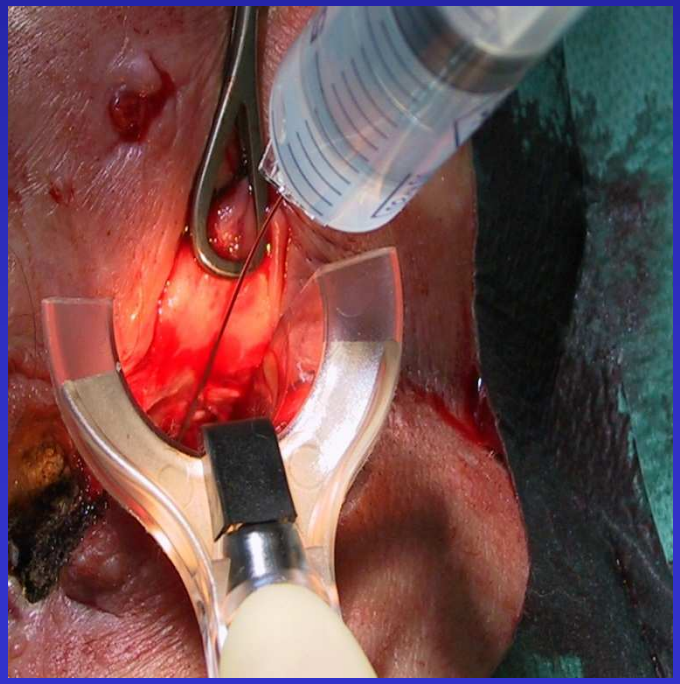
April, 2005

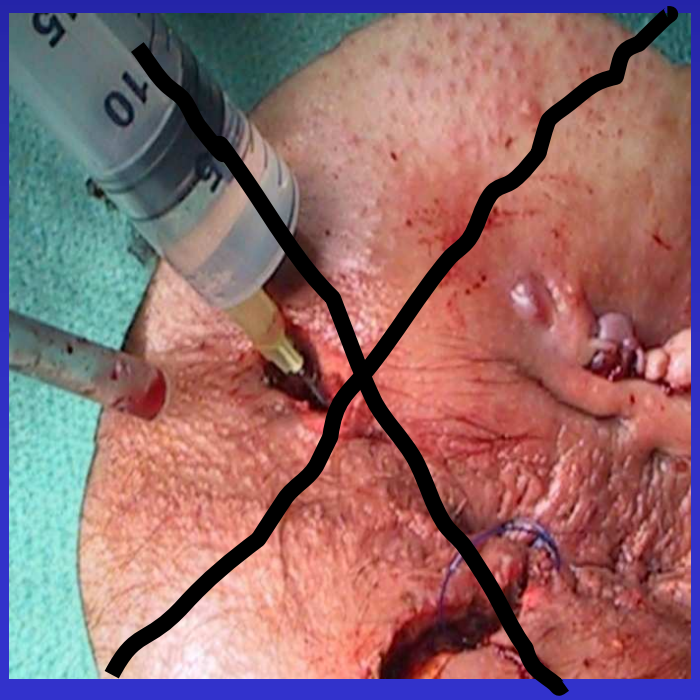
- **Mantoux test before first infusion**
- **EUA (Spinal or General anesthesia)**
- **15-21mg / patient**
- **6 initial infusions at 0, 4 and 8 , 12, 16, 20 weeks and eventually subsequent infusions every 4 weeks**

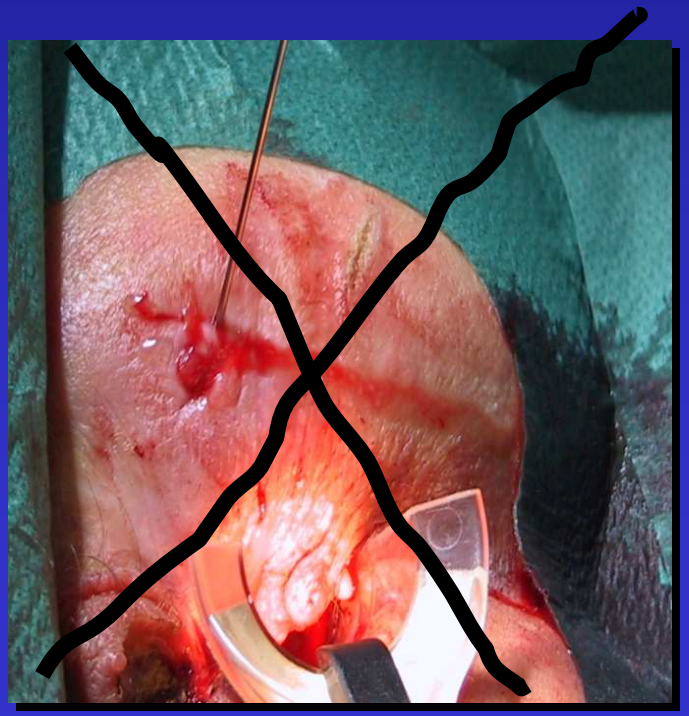
LOCAL INJECTION OF BIOLOGICAL DRUGS

TECHNIQUE

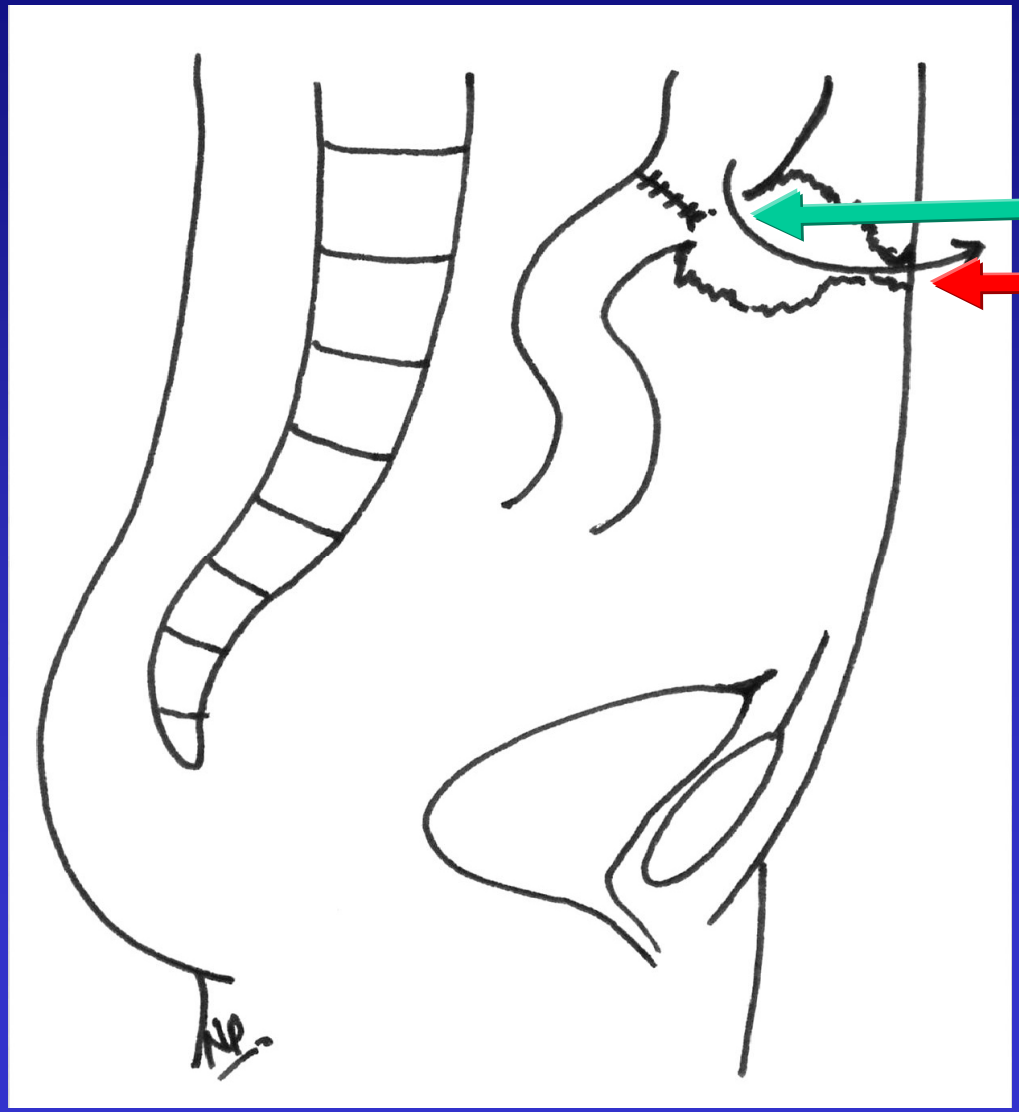
Injection of drug only at the internal opening in order to avoid external opening's closure and recurrence of abscess







GOLD STANDARD OF DIGESTIVE-CUTANEOUS FISTULAS' TREATMENT

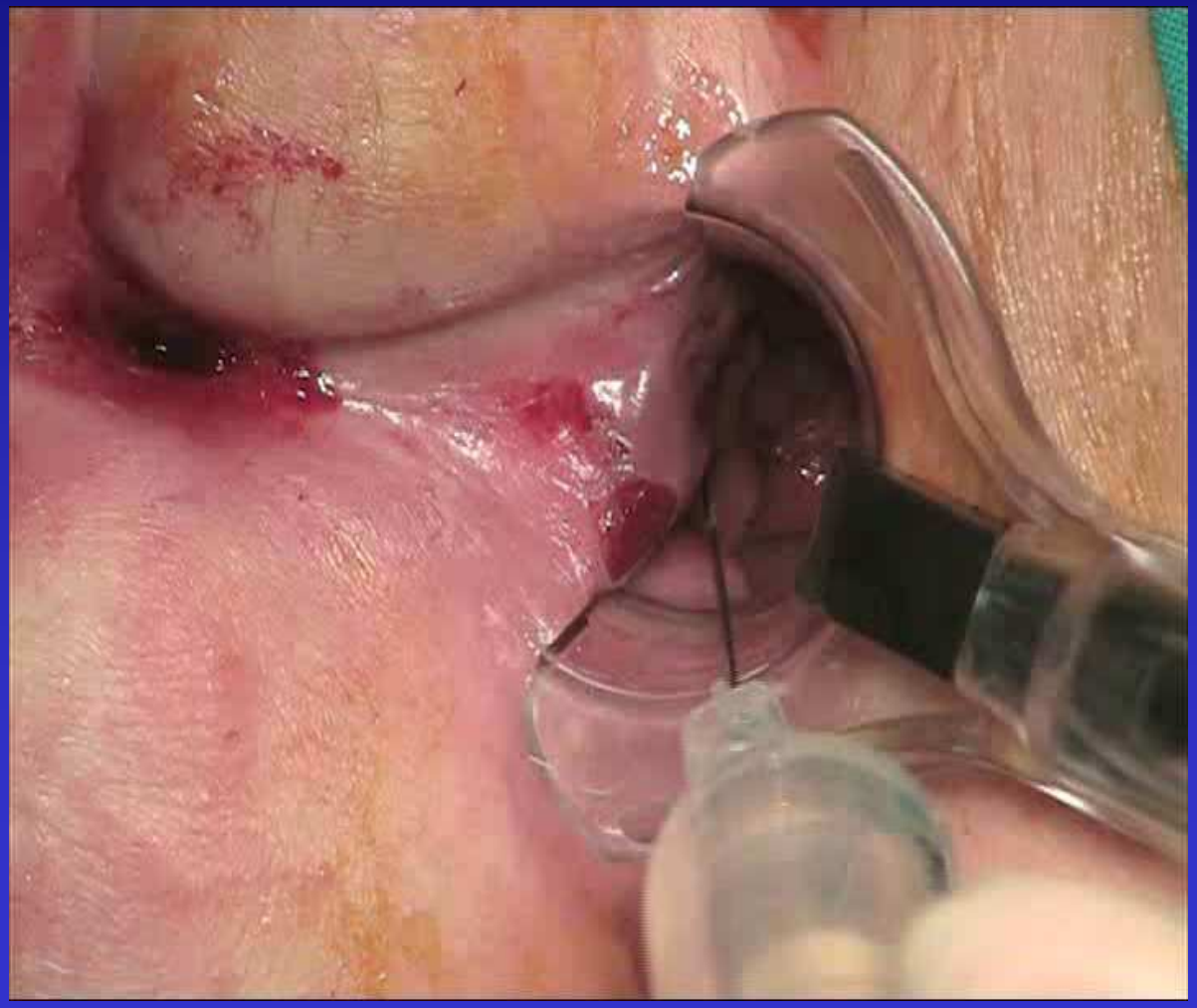


Primary end-point is fistula's healing with complete closure of internal opening (*"source"*)

Why is this issue often forgotten in perianal fistulas?

Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB



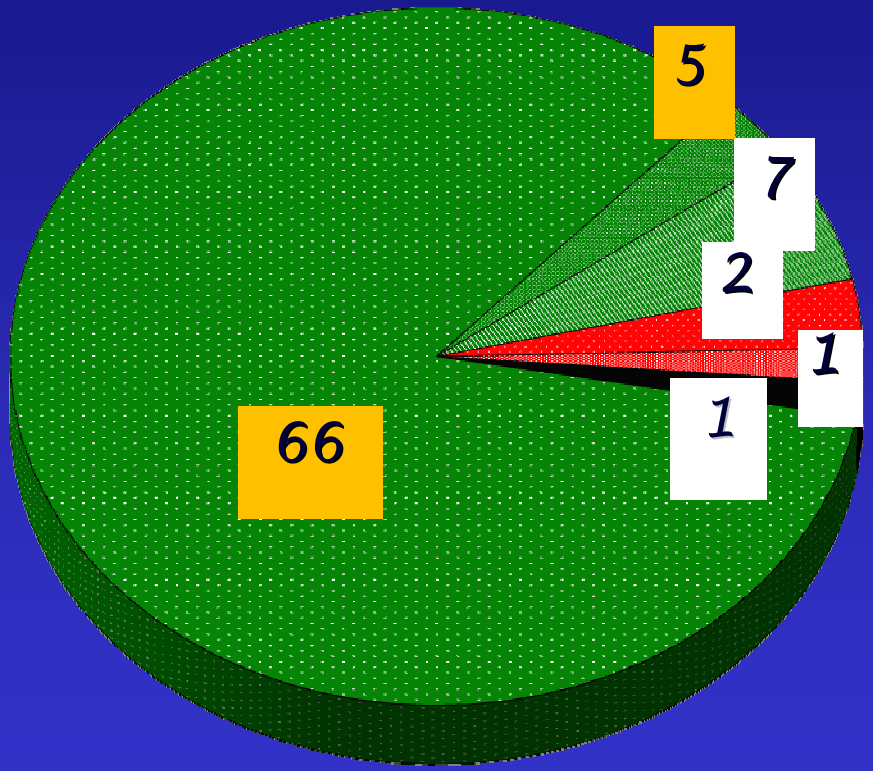
TECHNIQUE

Injection of Infliximab at the internal orifice

Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB

82 patients



Perianal Crohn's Disease

Contraindications to I.V. infusion

Associated colo - proctitis

Not responders to I.V. infusion

Surgical complications of IPAA

Pouch-vaginal fistula

Cuffitis

Pouch-anal fistula

Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB

Healed patients (“Grade 4”)

BEFORE

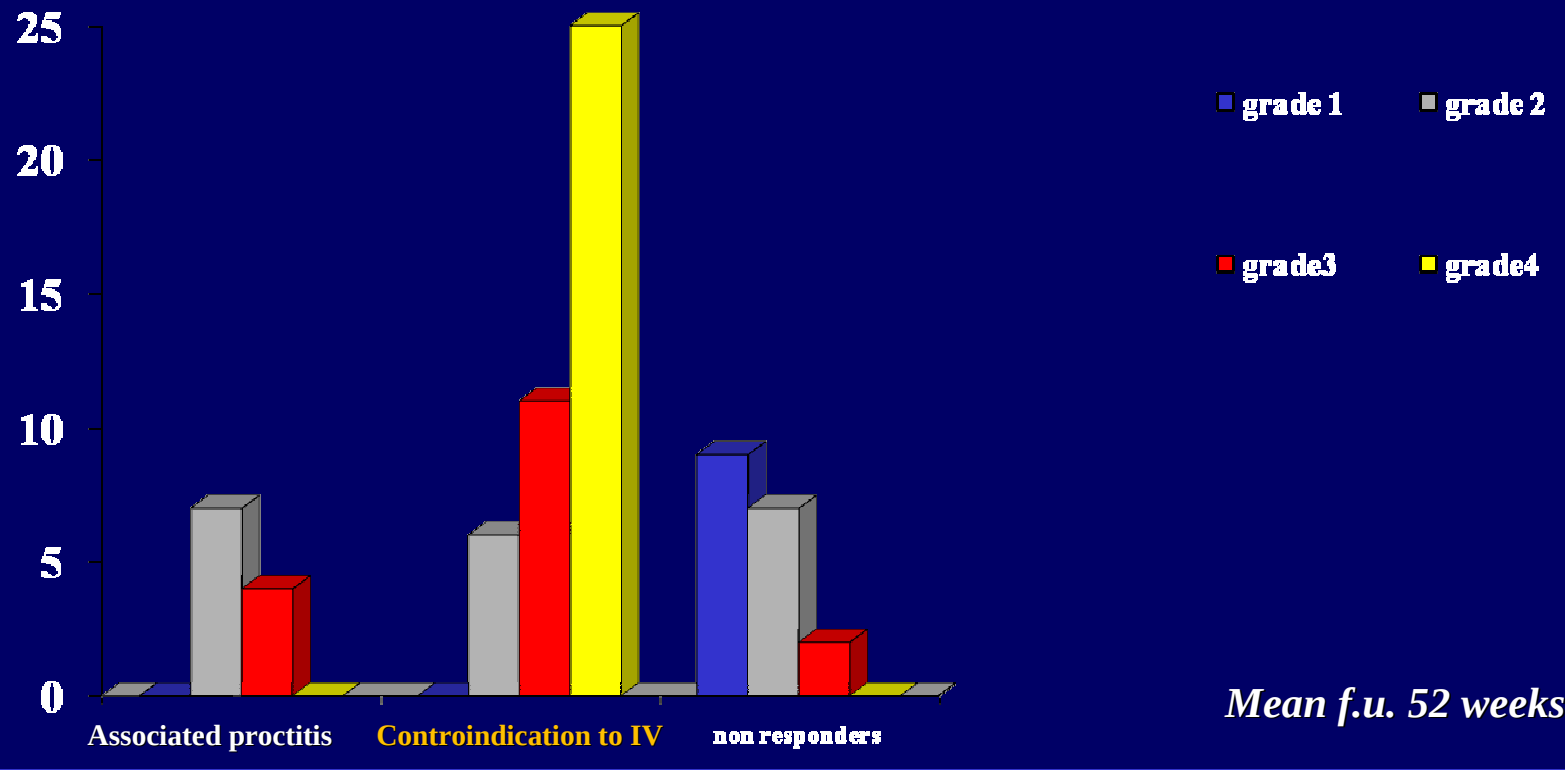
AFTER

Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB

Results (82 patients)

Overall success 64.7 %

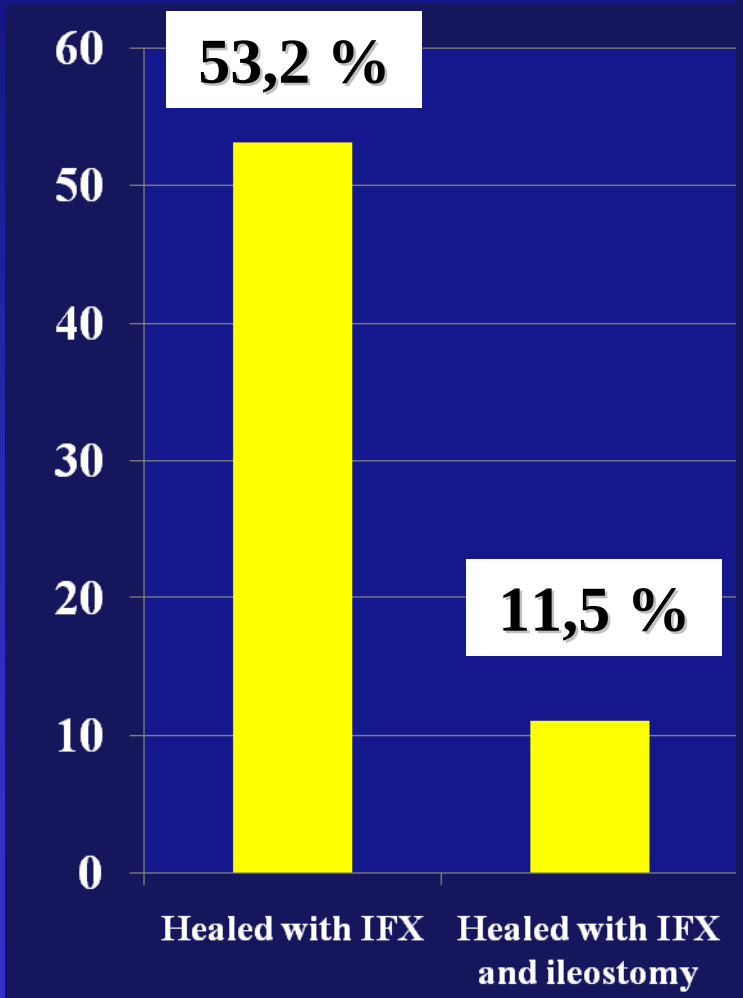


Mean f.u. 52 weeks

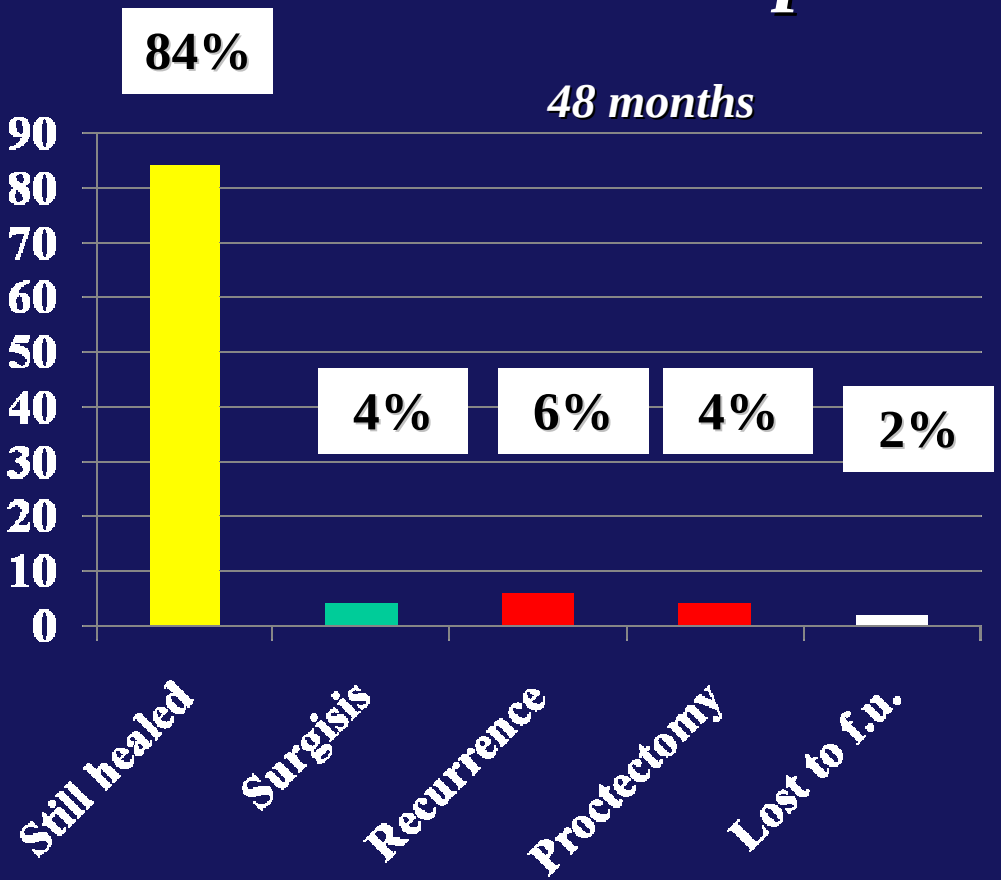
Surgical Unit, Bologna, 2012

LOCAL INJECTION OF INFLIXIMAB

Overall success 64.7 %



Follow up



Local Injection of adalimumab for perianal Crohn's Disease: Better than infliximab?

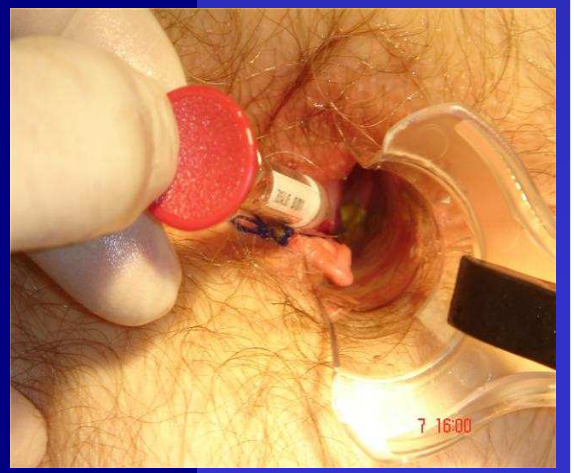
Poggioli G, Laureti S, Pierangeli F, Bazzi P, Coscia M, Gentilini L, Rizzello F, Gionchetti P

Inflamm Bowel Dis, 2010

34 pts treated

- *12 rescue therapy after local injection of Infliximab*
- *21 naïve therapy*

- **Injection of 40 mg every 15 days**
- **Outpatient treatment**
- **Consistence more convenient for local injection**
- **Same technique as Infliximab local injection**



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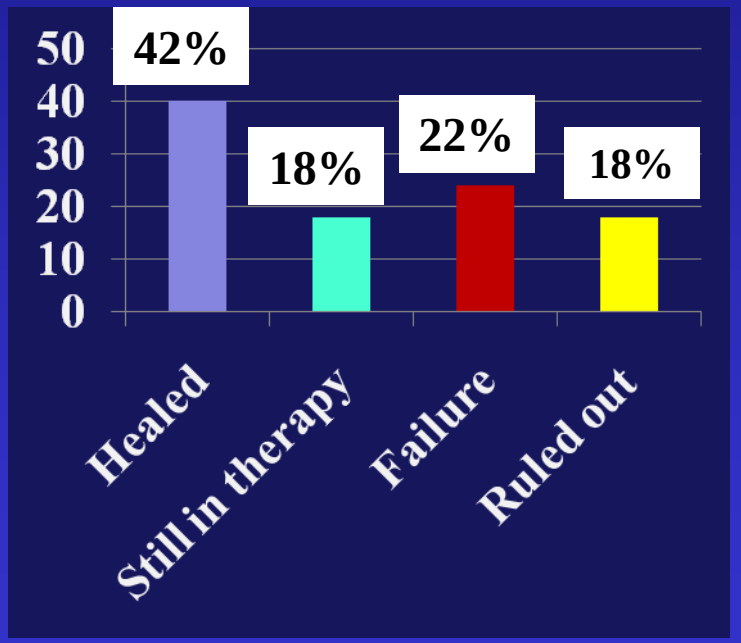
Inflamm Bowel Dis, 2010,

34 pts treated

RESULTS

- **42 %** 15 pts **healed (score 4)**
- **18 %** 5 pts **still in therapy pts**
- **22 %** 8 pts **failure** *(80% waiting for rescue surgical procedure)*
- **18 %** 6 pts* **ruled out**



** 1 adverse event – 1 ischemic heart disease – 1 pts with ileal stenosis- 2 pts lack of compliance for pain 1 lost to f.u.*

TREATMENT OF COMPLEX PERIANAL FISTULAS

WHAT ABOUT PATIENTS UNHEALED AFTER COMBINED SURGICAL AND BIOLOGICAL THERAPY

REVIEW

Emerging treatments for complex perianal fistula in Crohn's disease

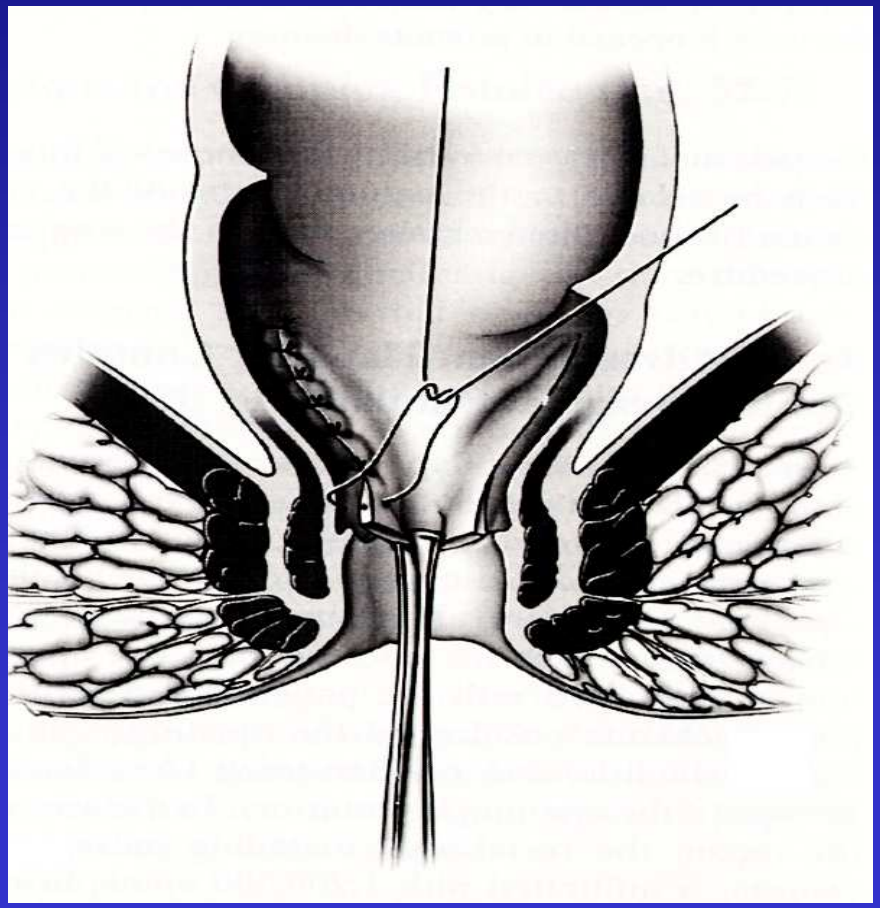
Carlos Taxonera, David A Schwartz, Damián García-Olmo

World J Gastroenterol, Sept 2009

Fibrin glue		
Abel *et al*[ ], 1993	Uncontrolled study of use of fibrin glue in 10 patients (2 Crohn's)	0/2 patients with Crohn's disease achieved healing
Cintron *et al*[90], 2000	79 patients (6 Crohn's) assigned to 3 types of fibrin glue treatment	2/6 Crohn's patients (33%) achieved healing (no drainage)
Lindsey *et al*[66], 2002	Randomized trial comparing fibrin glue with conventional surgery (fistulotomy or loose seton placement) in 42 patients (6 Crohn's and complex perianal fistula)	Healing (no drainage) in 2/6 Crohn's patients (33%) who received fibrin glue. No Crohn's patients received conventional surgery
Sentovich[81], 2003	Uncontrolled study: 48 patients (5 Crohn's) underwent seton placement followed by instillation of fibrin glue	Healing in 4/5 (80%) Crohn's patients
Zmora *et al*[82], 2003	Retrospective review of 37 patients with perineal fistula (7 Crohn's) treated with fibrin glue	Healing in 3/7 Crohn's patients (43%) (2 patients also treated with endorectal advancement flap)
Loungnarath *et al*[83], 2004	Retrospective review of 42 patients with perianal fistula (13 Crohn's) treated with fibrin glue	Lasting fistula healing in 4/13 (31%)
Singer *et al*[84], 2005	Randomized trial comparing fibrin glue + antibiotics, fibrin glue + surgery, and fibrin glue + antibiotic and surgery in 75 patients (3 Crohn's)	Treatment failed in all 3 Crohn's patients (fibrin glue + antibiotic in 1 patient and fibrin + antibiotic and surgery in 2 patients)
Intralesional infliximab		
Poggioli *et al*[68], 2005	Uncontrolled study of 15 Crohn's patients with complex perianal fistulas	Healing in 10/15 patients after 3-12 infusions
Asteria *et al*[69], 2006	Uncontrolled study of 11 Crohn's patients with complex perianal fistulas naïve to infliximab	8/11 patients responded (≥ 50% reduction in fistula drainage) to treatment
Adipose-derived stem cell (ASC) therapy with fibrin glue		
García-Olmo *et al*[72], 2005	Uncontrolled proof-of-concept study in patients with fistulizing Crohn's disease, including 1 perineal fistula	Perineal fistula healed after 8 wk
Garcia-Olmo *et al*[73], 2009	Randomized controlled phase II study comparing fibrin glue + ASCs with fibrin glue in 49 patients with complex perianal fistula (14 Crohn's)	Healing in 5/7 Crohn's patients (71%) in fibrin glue + ASCs group compared to 1/7 (14%) in the control group
Fistula plugs		
O'Connor *et al*[75], 2006	Uncontrolled study of fistula plug in 20 Crohn's patients with fistula tracts not amenable to fistulotomy	Success rate of 80%, lower in the case of complex fistulas
Schwandner *et al*[76], 2008	Uncontrolled study of 19 patients (7 Crohn's) with trans-sphincteric anorectal fistulas	Treatment success in 6/7 patients with Crohn's disease (86%)
Ky *et al*[77], 2008	Prospective analysis of 45 patients (20 with complex fistulas and 14 with Crohn's disease) receiving anal fistula plug	Healing in 4/14 Crohn's patients (29%) after a median follow-up of 6.5 mo

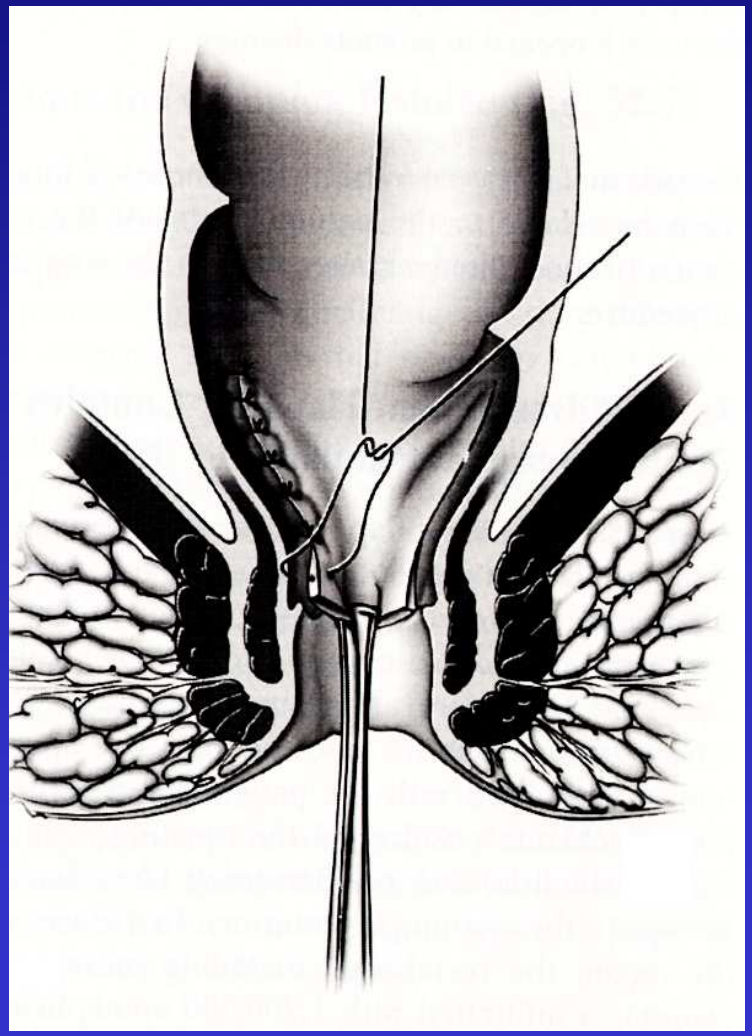
ENDORECTAL ADVANCEMENT FLAP

How to do it



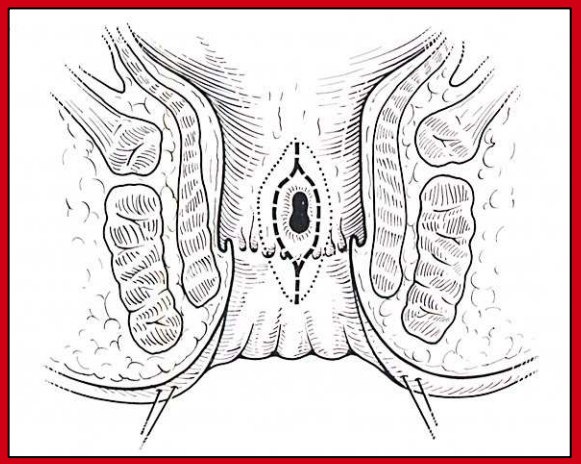
The flap is advanced over the internal opening and closed

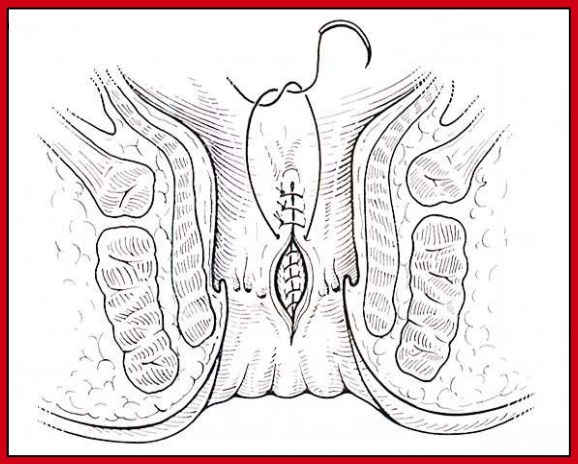
ENDORECTAL ADVANCEMENT FLAP

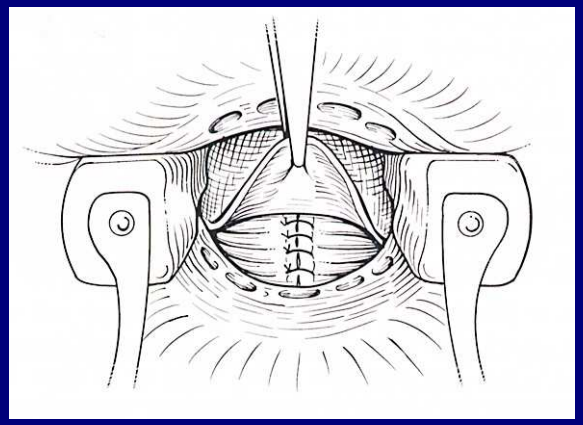


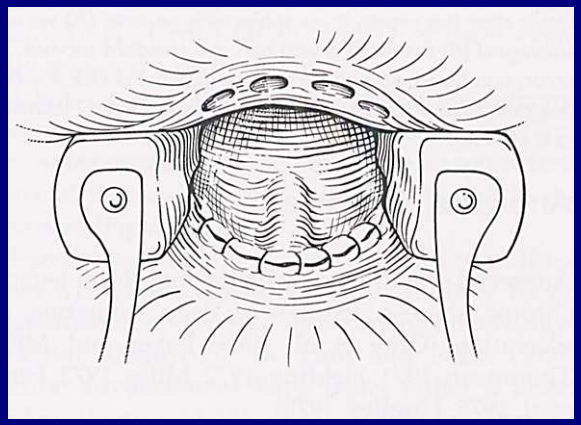
- Complex fistulas
  - *transphincteric*
  - *suprasphincteric*
  - *selected extrasphincteric*
  - *recto-vaginal*
- **Only when anorectal disease is quiescent**
- Not useful if active proctitis, undrained sepsis, rectal stricture, severe sphincter
- No sphincter division, no extended wounds

ENDORECTAL ADVANCEMENT FLAP









Fazio, 1997

- **48** pts with RV fistula
- 13 pts treated with TPC (9) or seton (4)
- 35 pts with transanal repair (linear or curvilinear)
- **19/35 (54%)** healed with **first** operation

Surgical Unit, Bologna, 2012

FLAP

ENDORECTAL ADVANCEMENT FLAP

43 pts with perianal, RV or pouch-anal fistula

- **8 pts with ileo/colostomy**
- **22 (51 %) healed with first operation**
- **14 healed with repeat operation (32 %)**

Overall Success 83 %

INNOVATIONS

BIOLOGICAL GLUES

- **Mixed-cell adhesive foam, delivered as a liquid and immediately begins polymerizing, and expanding to seal the tissue and promote cellular aggregation.**

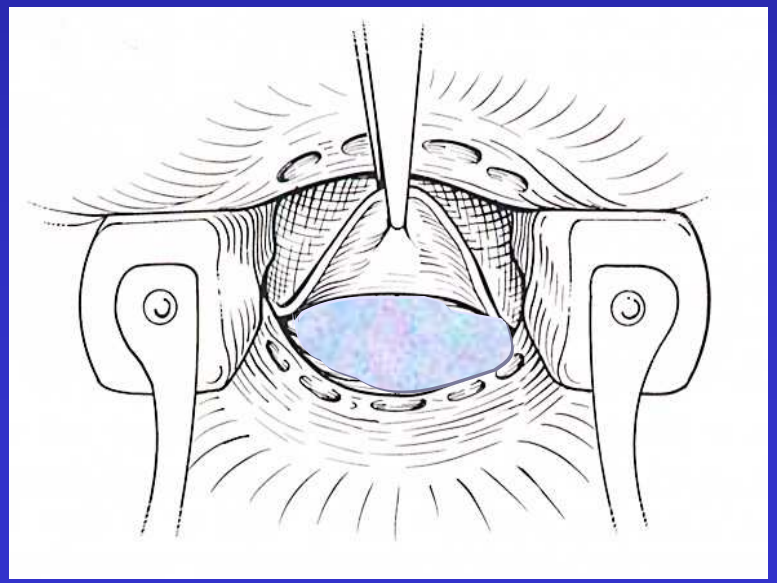
- **dual mechanism of action:**
  1) Crosslinking proteins and adhering strongly to tissue, providing a mechanical barrier
  2) Providing pores for blood to enter, leading to cellular aggregation

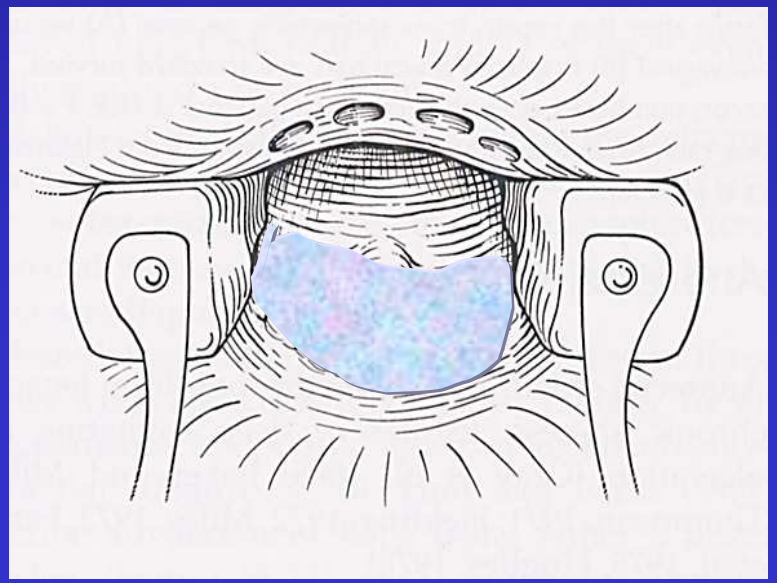
- **Over 3 times stronger than fibrin sealants**

INNOVATIONS

BIOLOGICAL GLUES

- Injection in the fistula tract then closure of internal orifice and mucosal flap reinforced with glue
- Safe procedure with no handling of sphincters





INNOVATIONS

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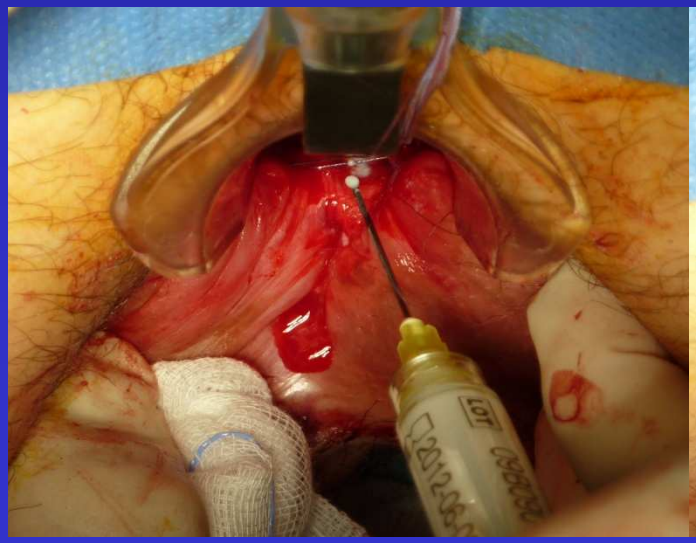
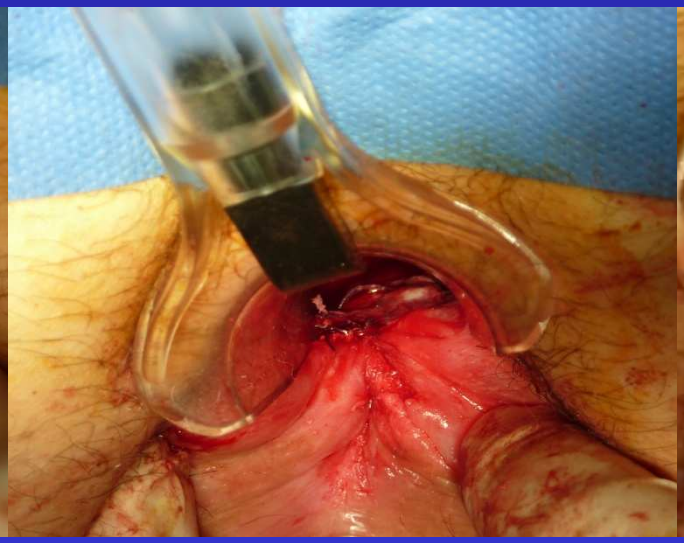
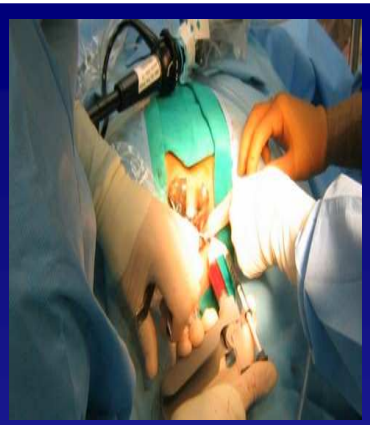






Surgical Unit, Bologna, 2012

INNOVATIONS

BIOLOGICAL GLUES

- **Injection in the fistula tract then closure of internal orifice and mucosal flap reinforced with glue**
- **Safe procedure with no handling of sphincters**

8 pts with perianal or RV fistula

- **2 pts with ileo/colostomy**
- **4 (50 %) healed with first operation**
- **2 healed with repeat operation (25 %)**

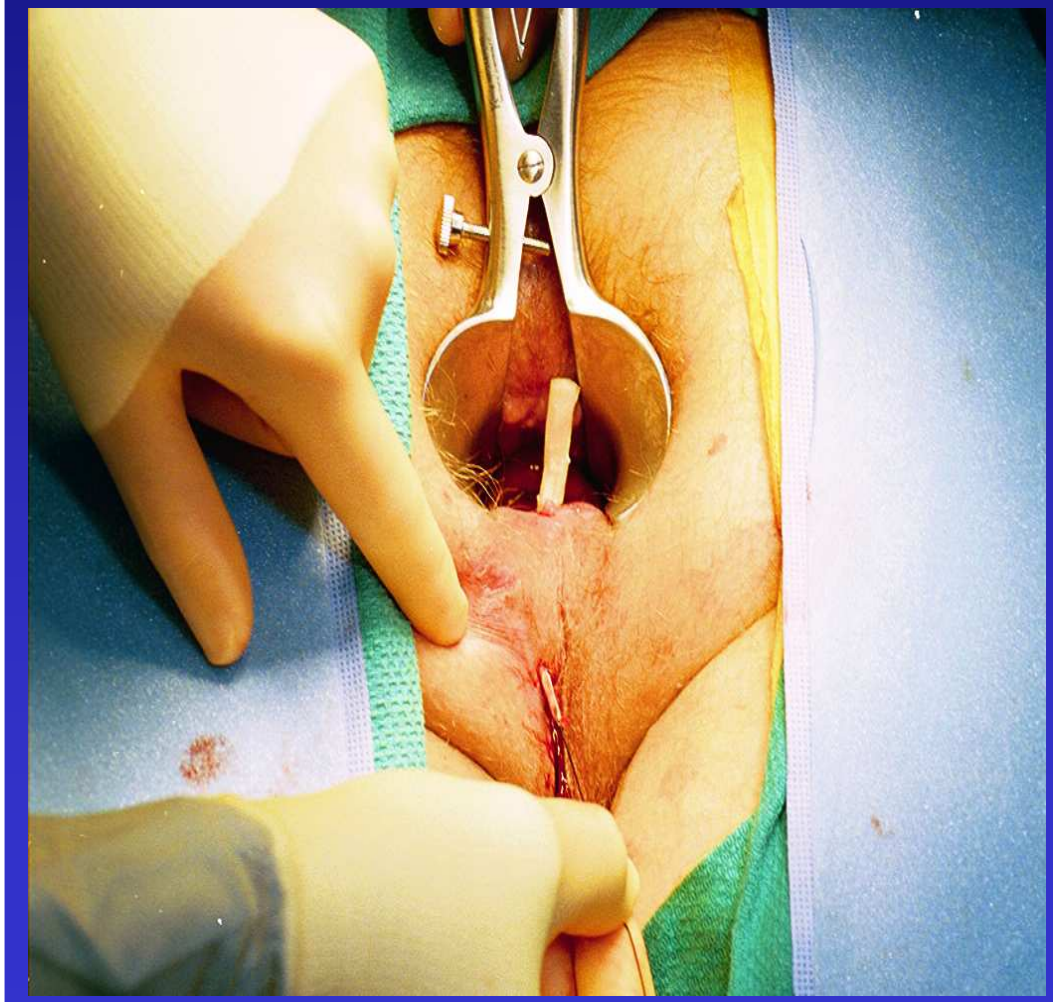
Overall Success

75 %

INNOVATIONS

BIOLOGICAL PROSTHESIS

SURGISIS ™

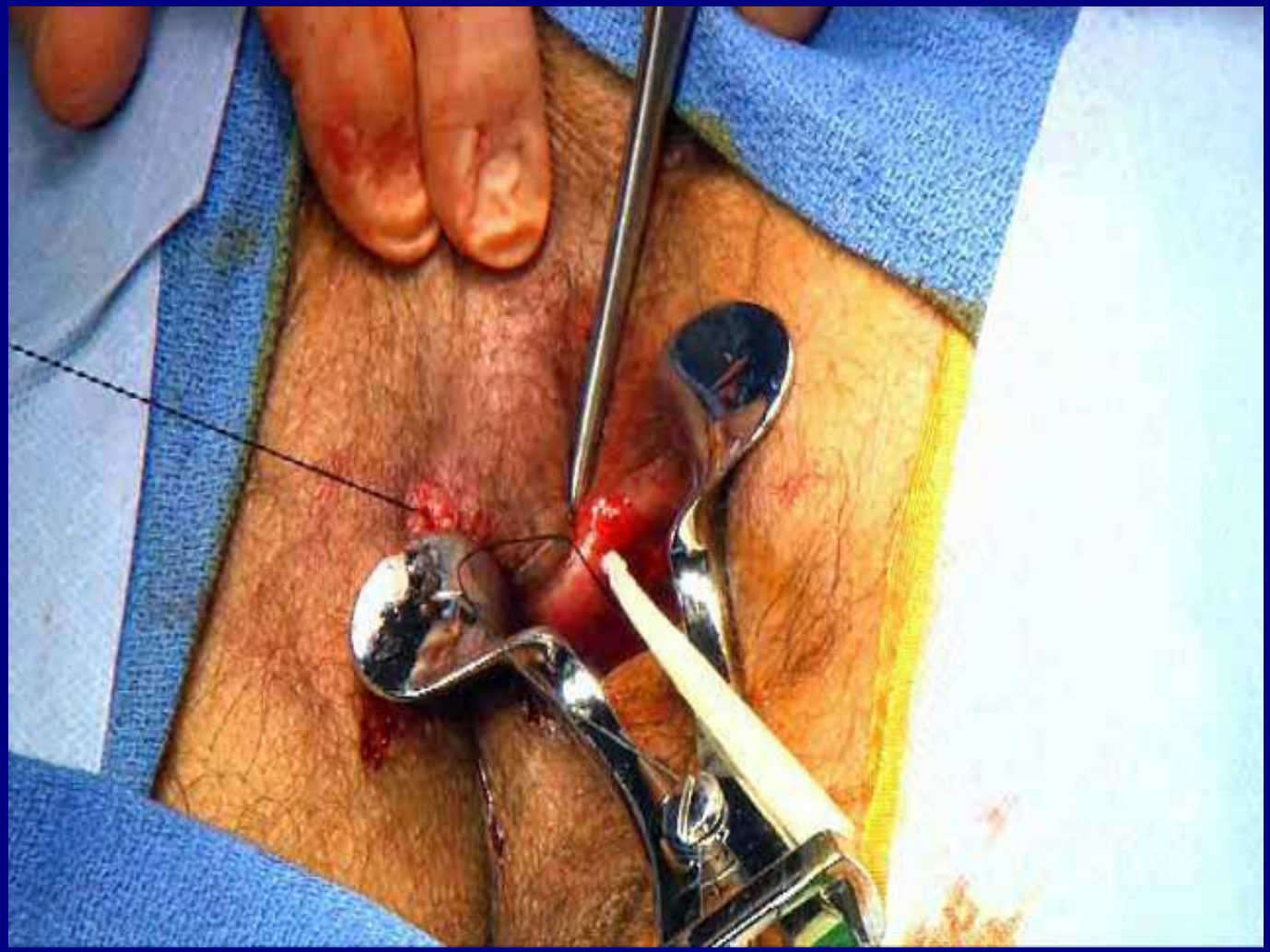


- Collagen conical plug made of porcine intestinal submucosa
- Suturable into primary opening → **the plug acts as a scaffold for new tissue to grow into**
- Safe modality / No septic complications
- Further prospective studies are needed

INNOVATIONS

BIOLOGICAL PROSTHESIS

SURGISIS ™



Efficacy of the anal fistula plug in complex anorectal fistulae

D. K. Thekkinkattil*, I. Botterill*, N. S. Ambrose*, L. Lundby†, P. M. Sagar*, S. Buntzen† and P. J. Finan*

*John Goligher Colorectal Unit, General Infirmary at Leeds, Leeds Teaching Hospitals NHS Trust, Leeds, UK and †Department of Surgery, Aarhus University Hospital, THG, Aarhus, Denmark

Colorectal Disease 2009

Outcome and anatomical classification

Type of fistula	Healed (n = 20)	Nonhealed (n = 25)	P-value*
Trans-sphincteric with radial tracts (n = 29)	16	12	0.224
Supra levator (n = 2)	0	2	P=N.S.
Horseshoe (n = 5)	2	4	
Rectovaginal (n = 7)	1	5	
Pouch vaginal (n = 3)	1	2	

Outcome and vaginal involvement

	Healed	Nonhealed	P-value*
Anorectal fistula without vaginal involvement	18	18	0.260
Anorectal fistulae with vaginal involvement	2	7	P=N.S.

Outcome and number of fistulas

Number of tracks	Healed	Nonhealed	P-value*
Single	19	21	0.362
Multiple	1	4	P=N.S.

CONCLUSION

This study failed to reproduce the excellent success rates reported by other studies

The complex nature of the fistulae selected may be the reason for the low success rate

Surgical Unit, Bologna, 2010-2012

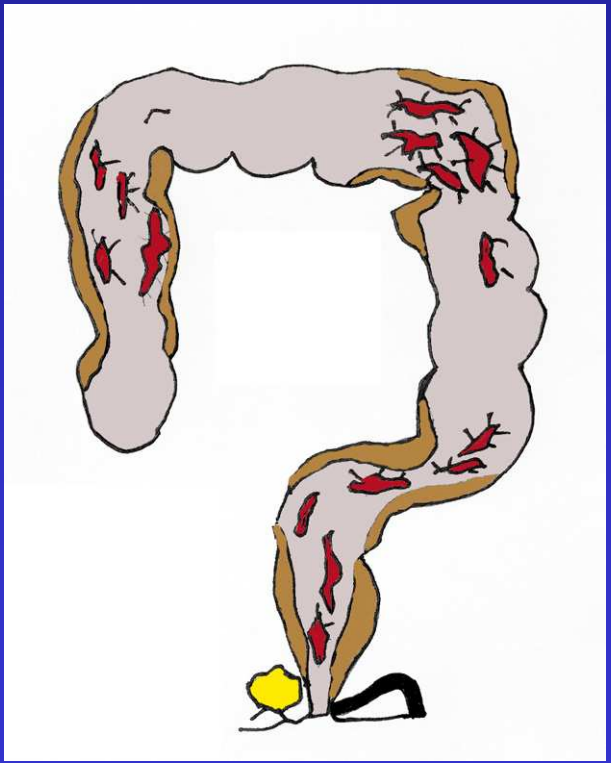
Complex Anal fistula plug repair

14 pts

TYPE	PTS	PREVIOUS TREATMENT	F.U. wks	HEALED
Horse-shoe	**7**	Surgery, Local Infliximab	12	71%
Suprasphincteric	**2**	Surgery, *Infliximab*	4	100%
Recto-vaginal	**1**	Local Infliximab	10	No
Pouch-anal, Pouch-vaginal	**4**	Local Infliximab	2	25%

COLONIC DISEASE AND RECTAL INVOLVEMENT

In established colonic disease with SEVERE rectal involvement total proctocolectomy whith permanent ileostomy has to be performed



COULD the anti-TNF α MODIFY THE SURGICAL APPROACH ?

CONTROVERSIES

Proctocolitis and complex perianal disease

DIVERSION OF FECAL STREAM

Originally proposed in Oxford since 1960 so called "Split Ileostomy"

Simple procedure expecially with laparoscopic approach

ACTUAL INDICATION

- **Additional management option in cases of severe refractory disease but very low success rates in terms of both disease outcome and prospects for restoration of intestinal continuity**
- **This is not improved with biological therapy**

PERIANAL CROHN'S DISEASE

Outcome of fecal diversion

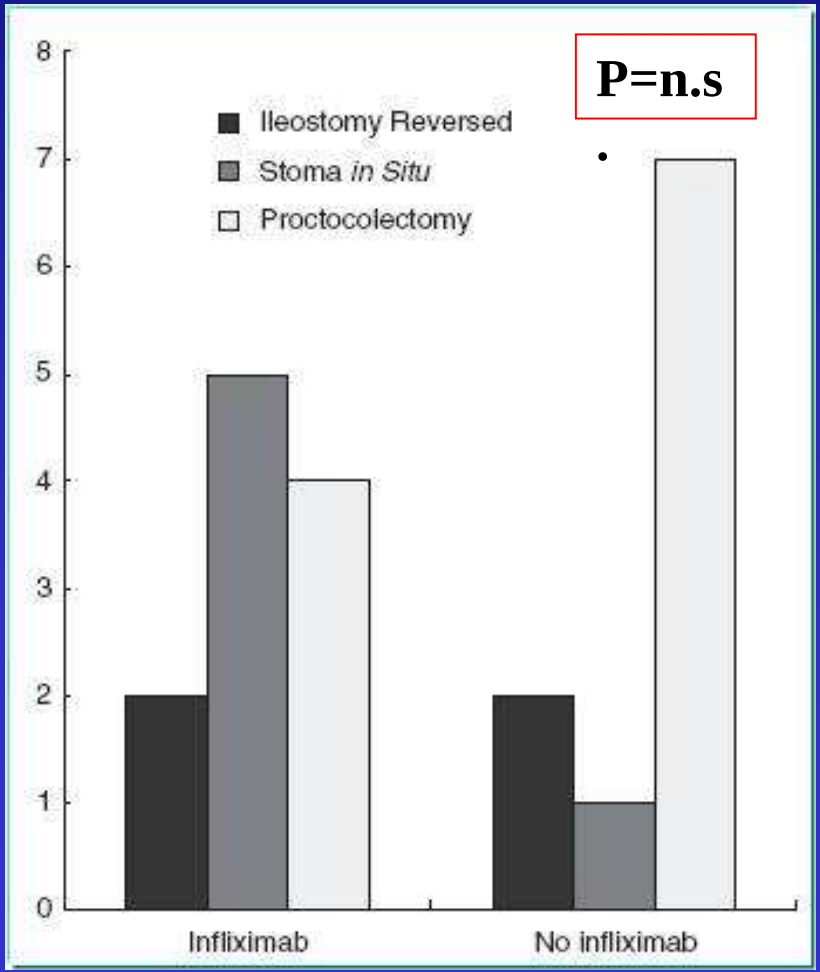
Yamamoto, 2000

OUTCOME	N.	FAILURE	EARLY REMISSION	LATE RELAPSE	COMPLETE REMISION	Restorative of intestinal continuity
Overall	31	6	25	17	8	3
Perianal sepsis	13	4	9	5	4	2
Anal ulcer	3	0	3	3	0	0
Anorectal fistula	9	0	9	5	4	1
Rectovaginal fistula	6	2	4	4	0	0

Faecal diversion in the management of perianal Crohn's disease

M. K. H. Hong*, A. Craig Lynch†§¶, S. Bell‡, R. J. Woods*, J. O. Keck*, M. J. Johnston* and A. G. Heriot*§¶

*Department of Colorectal Surgery, St Vincent's Hospital, Melbourne, Victoria, Australia,



21 pts with extesive colitis/proctocolitis and complex perianal disease

Faecal diversion, surgical drainage of perianal disease ± IFX

"Patients undergoing temporary faecal diversion …. have less than a 20% likelihood of restoration of intestinal continuity. These rates do not appear to have improved with the introduction of episodic biological therapy (infliximab)"

Surgical Unit, Bologna, 2012

Surgical treatment of Crohn's Colitis: 233 pts

In the pre BIOLOGICAL era *

51 pts

45 %

STC + IRA

13 %

SECONDARY PROCTECTOMY + ileostomy

22 %

STC + ileostomy

61%

FINAL FATE = ILEOSTOMY

33 %

TPC + ileostomy

* *Before 2002*

Surgical Unit, Bologna, 2012

Surgical treatment of Crohn's Colitis: 233 pts

In the BIOLOGICAL era *

182 pts

40 % (73 pts)

STC + IRA

5 % (4 pts)

Delayed loop ileostomy for perianal disease

75 % healed after biological therapy

55 % (100 pts)

Colectomy

5 % (9 pts)

TPC + ileostomy

** After 2002*

Surgical Unit, Bologna, 2012

Surgical treatment of Crohn's Colitis: 233 pts

In the BIOLOGICAL era *

182 pts

40 % (73 pts)
STC + IRA

55 % (100 pts)
Colectomy

5 % (9 pts)
TPC + ileostomy

67 %
Treated by *BIOLOGICAL DRUGS*

46.3 %
IRA

12 % Delayed proctectomy
(mean time: 4,5 yrs)

37.3 %
Still under biological therapy

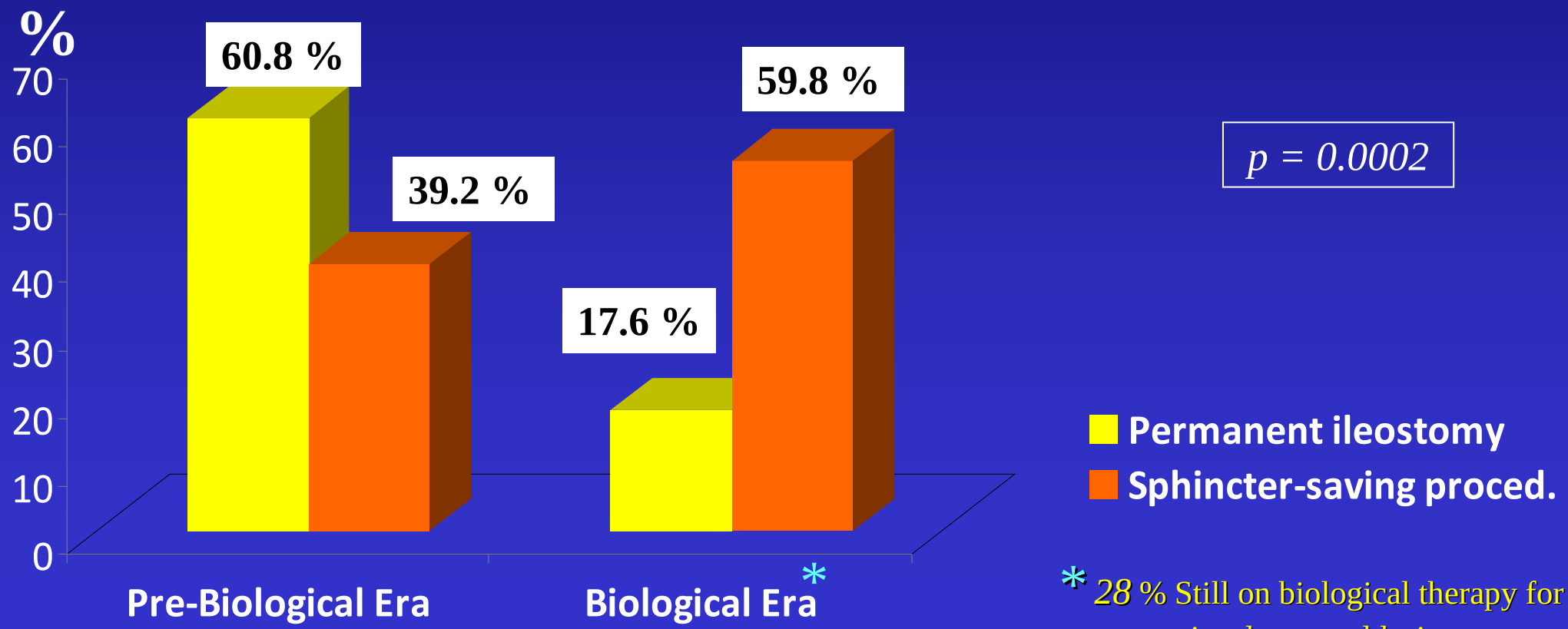
16.4 %
Proctectomy and permanent ileostomy

** After 2002*

Surgical Unit, Bologna, 2012

Surgical treatment of Crohn's Colitis

Permanent ileostomy vs *Sphincter-saving procedure*



* *28* % Still on biological therapy for perianal or rectal lesions

COLONIC DISEASE AND ANORECTAL INVOLVEMENT

SURGICAL OPTIONS

Fecal diversion
Loop ileostomy

Sub-total colectomy, ileostomy and Hartmann pouch

Total proctocolectomy with permanent ileostomy

↓

ANTI-TNF-α THERAPY

↓

SPHINCTER-SAVING PROCEDURES