

# Perineal reconstruction after abdominoperineal excision for low rectal cancer.

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**HeSRU**

EXETER SURGICAL HEALTH SERVICES RESEARCH UNIT

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SCHOOL

# NBOCA 2020 – DATA BEFORE COVID

**Table 6.1**

Management of rectal cancer patients reported to NBOCA, by audit year

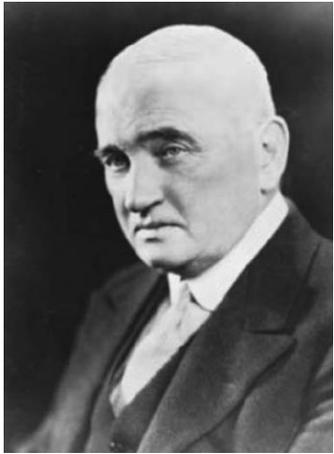
	2014–15		2015–16		2016–17		2017–18		2018–19	
	N	%	N	%	N	%	N	%	N	%
Total rectal cancer patients	<b>8,864</b>		<b>8,364</b>		<b>8,308</b>		<b>8,608</b>		<b>8,454</b>	
Major resection	4,846	54.7	4,479	53.6	4,487	54.0	4,488	52.1	3,899	46.1
Local excision	591	6.7	595	7.1	607	7.3	625	7.3	586	6.9
Non-resectional surgery	677	7.6	617	7.4	594	7.1	603	7.0	610	7.2
No surgery	2,750	31.0	2,673	32.0	2,620	31.5	2,892	33.6	3,359	39.7

**Table 6.4**

Major Resection procedure performed, by year of surgery

	2014–5		2015–16		2016–17		2017–18	
	N	%	N	%	N	%	N	%
Total	<b>3,597</b>		<b>4,361</b>		<b>4,223</b>		<b>4,292</b>	
Anterior Resection	2,299	63.9	2,742	62.9	2,615	61.9	2,632	61.3
APER	851	23.7	1,118	25.6	1,108	26.2	1,149	26.8
Hartmann's	357	9.9	381	8.7	394	9.3	428	10.0
Other	90	2.5	120	2.8	106	2.5	83	1.9

# 2000s - REDISCOVERING MILES



## **A Method of Performing Abdomino-Perineal Excision for Carcinoma of the Rectum and of the Terminal Portion of the Pelvic Colon (1908)\***

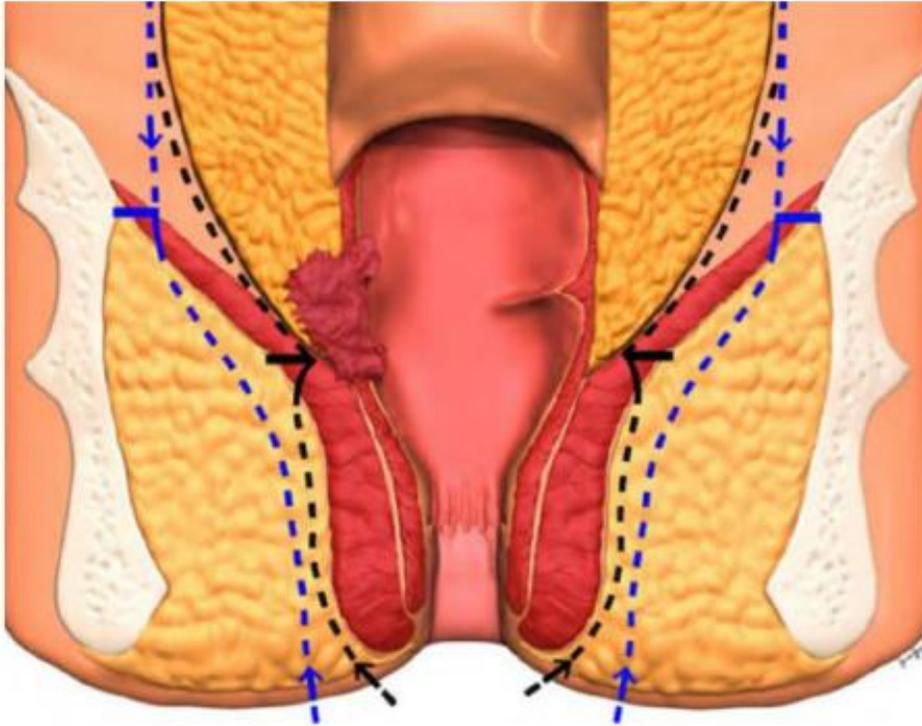
W. Ernest Miles, F.R.C.S., L.R.C.P.

The edges of the pelvic peritoneum are now sutured so as to re-establish the pelvic floor.

After reflecting the skin on either side to the requisite extent, the coccyx is removed and the interval between the levatores ani defined. These muscles should be divided as far outwards as their origin from the "white line" so as to include the lateral zone of spread.

# EXTRALEVATOR APE

West et al BJS 2010



- Compared to low AR, traditional APE had:
  - higher CRM +ve rates
  - high local recurrence
  - worse survival

# EXTRALEVATOR APE

- ELAPE vs “Standard” APE:

lower involved CRM (9.6% v 15.4%)

lower local recurrence (6.6% v 11.9%)

Stelzner et al. Int J Colorectal Dis 2011

lower bowel perforation (0% v 16.7%)

lower 5yr local recurrence (5.9% v 18.2%)

Stelzner et al. Int J Colorectal Dis 2016

lower intra-op perforation

Negoi et al. Am J Surg 2016



- ELAPE vs “Standard” APE:

no difference in DFS & OS

Klein et al. Int J Colorectal Dis 2016

more perineal morbidity (32% v 11%)

Asplund et al. Int J Colorectal Dis 2015

no difference in CRM or perforation

Zhou et al. Colorectal Dis 2015

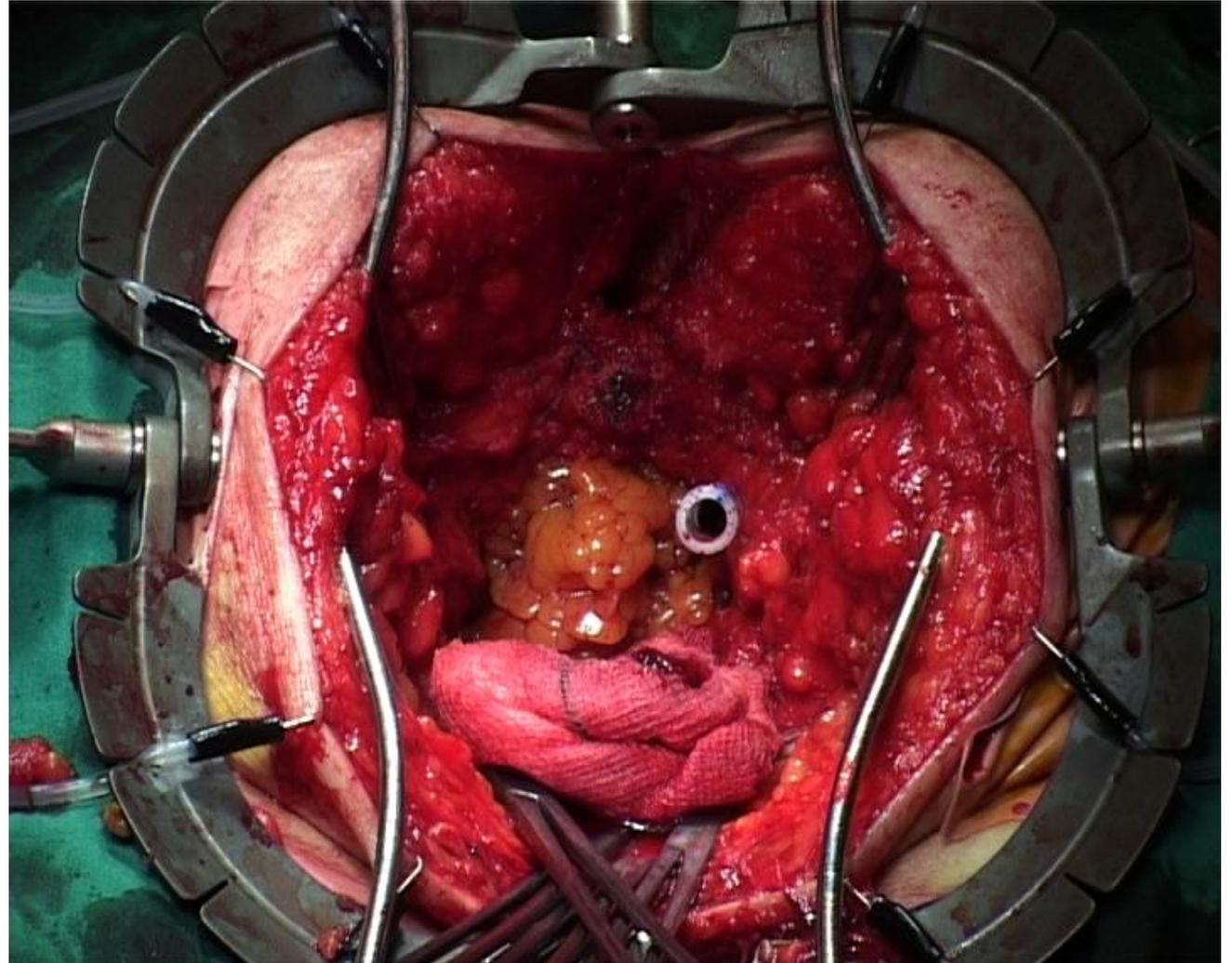
no differences in anything!

Ortiz et al. BJS 2014



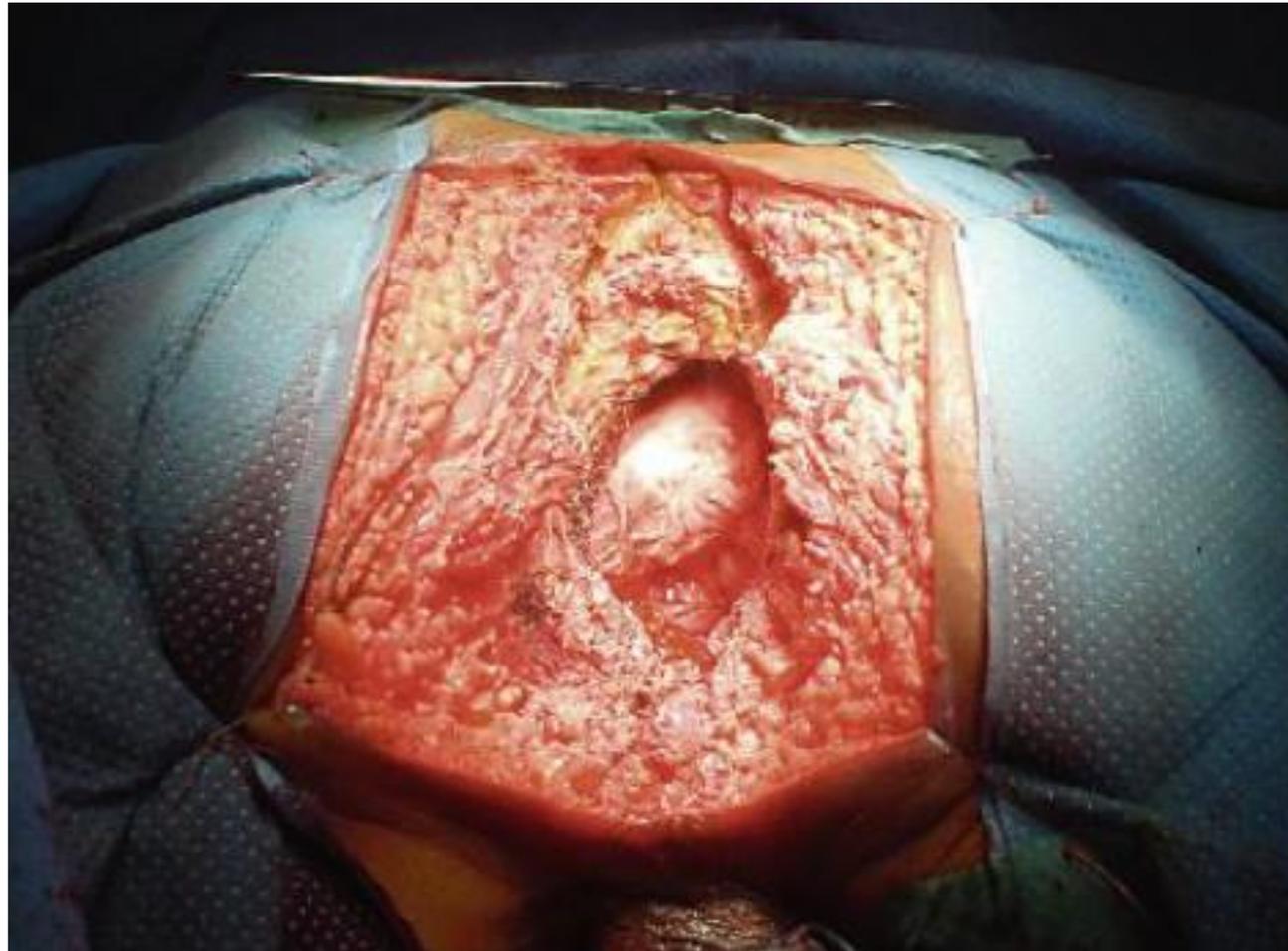
# THE PROBLEM

- Large perineal defect
- Increasing use of neoadjuvant (C)RT
  - Wound dehiscence
  - Delayed healing
  - Infection
- Reconstructing perineum:
  - Bulk / volume
  - Strength
  - Skin



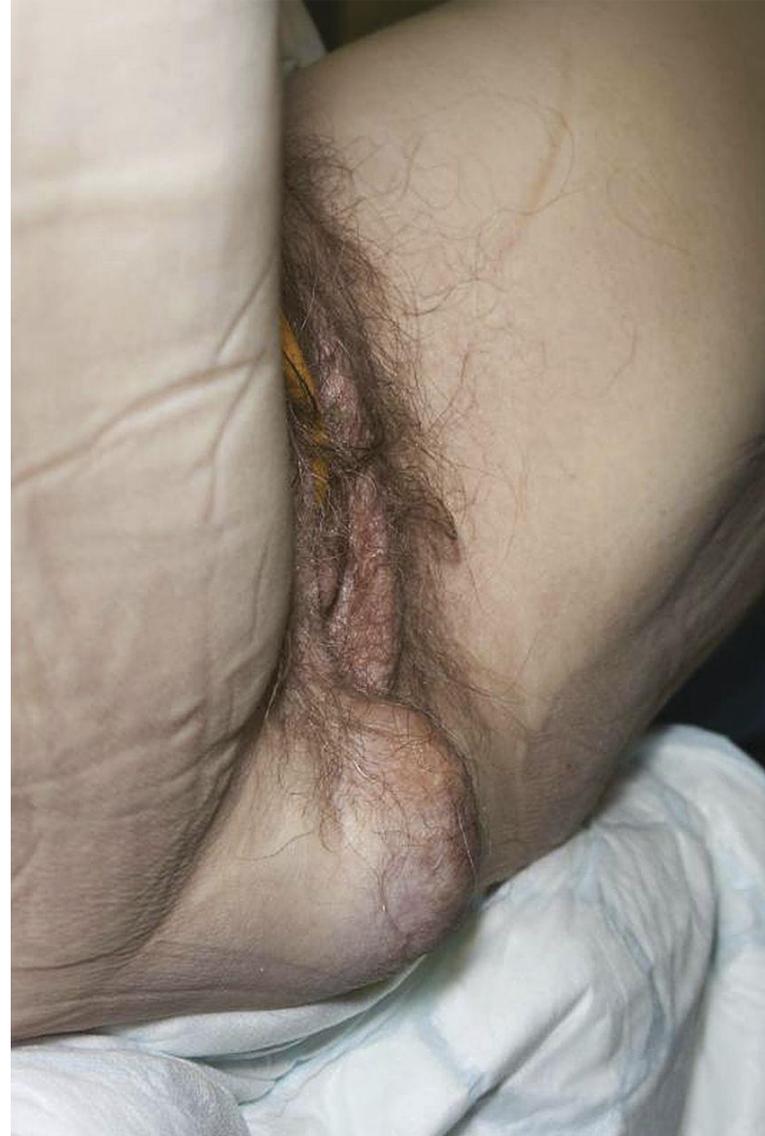
# EXTENDED SURGERY

- Pelvic Exenteration
- Salvage APE for anal cancer



# WHICH OUTCOME?

- Wound healing
- Complications
- Perineal hernia
- Pain
- Function
- Quality of life



# WHICH OUTCOME?

- Wound healing
- Complications
- **Perineal hernia**
- Pain
- Function
- Quality of life



# PERINEAL HERNIA DIAGNOSIS

- History
  - Pain / dragging
  - Urinary symptoms
  - Bowel obstruction
- Examination
  - Bulge
  - Cough impulse
- Radiology
  - CT
  - MRI



# PERINEAL HERNIA PREVALENCE

- Postoperative (@ 1year)

APE 1%

Exenteration 3 – 10%

- Rapid rise in published cases – real vs apparent?

- Changes in:

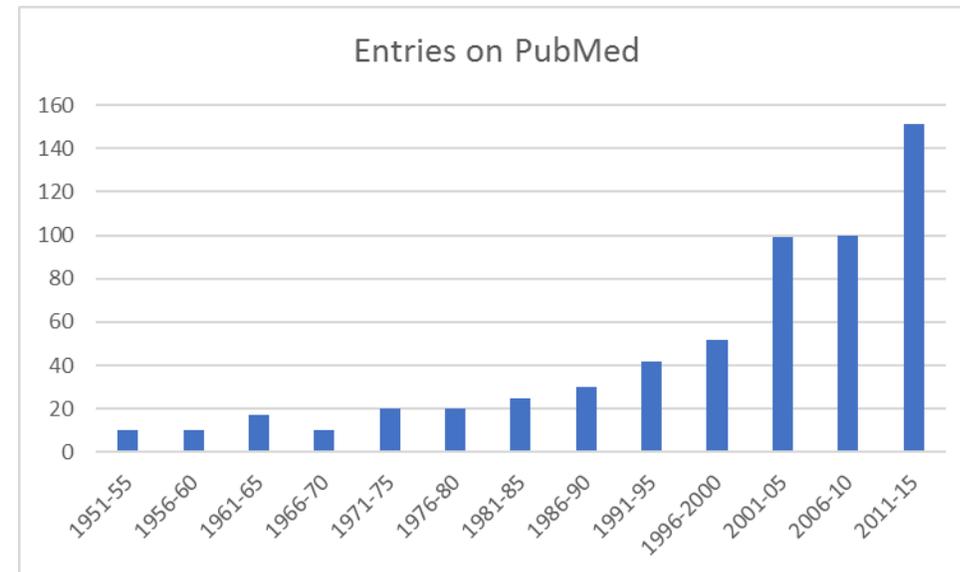
Patient factors / comorbidity

Surgery

Neoadjuvant CRT

Survival / Follow up

Diagnostics



# PERINEAL HERNIA AFTER ELAPE

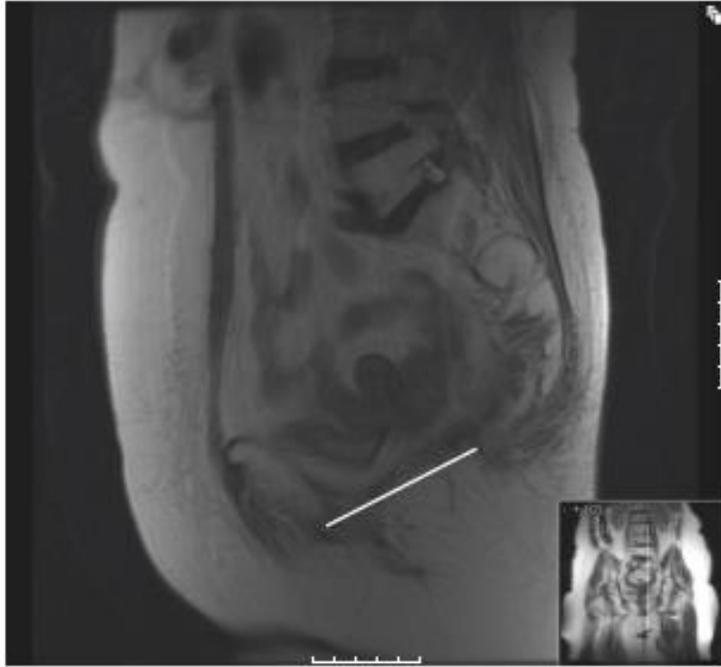


FIGURE 1: T<sub>2</sub>-weighted sagittal view. Patient lying supine with breath held. White line represents “modified pubococcygeal” line. The pelvic floor has been replaced by Permacol following cylindrical abdominoperineal excision.

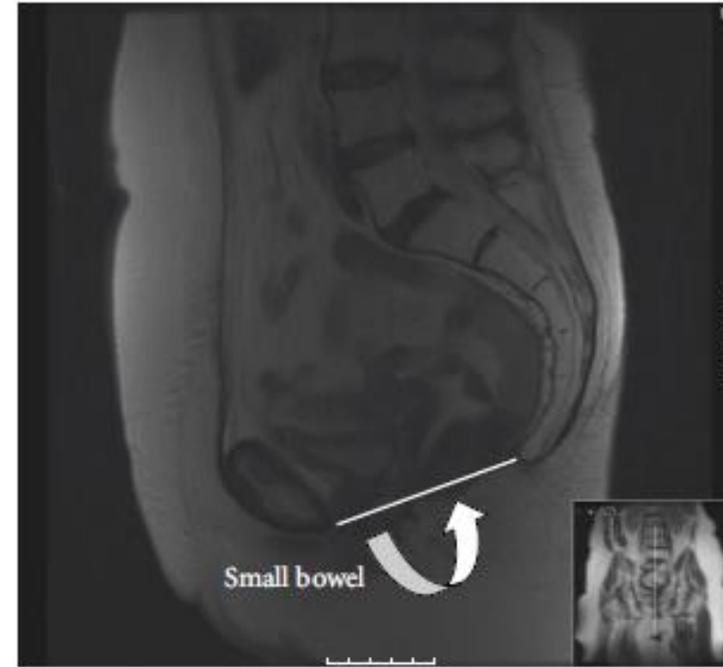
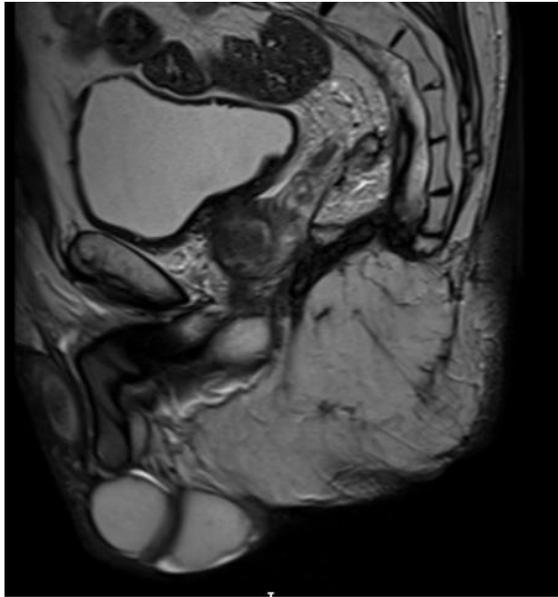


FIGURE 2: T<sub>2</sub>-weighted sagittal view. Patient in supine position performing a Valsalva. The modified pubococcygeal line is seen. The downward migration of the small bowel (curved arrow) below this line is <1 cm indicating an intact reconstructed pelvic floor.

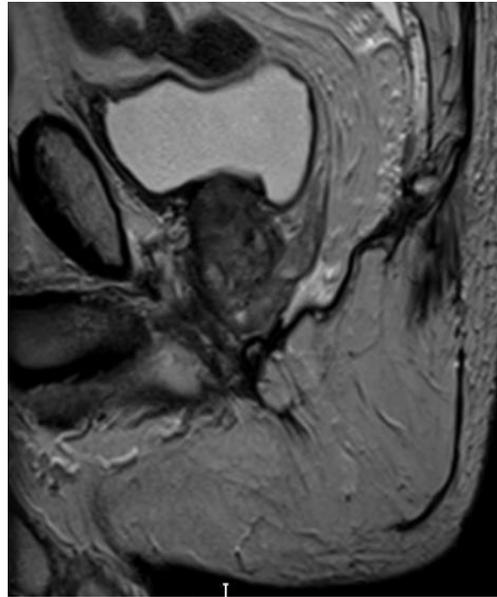
- Need for a standardised definition after levators have been excised.
- Applicable to primary closure / flap / mesh

# PERINEAL HERNIA – MRI & CT

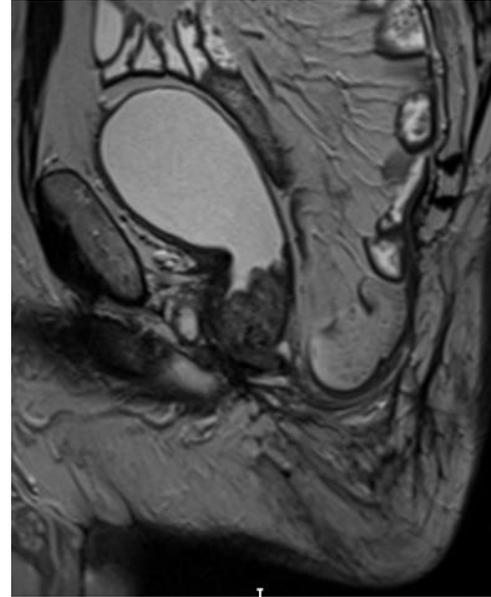
No hernia



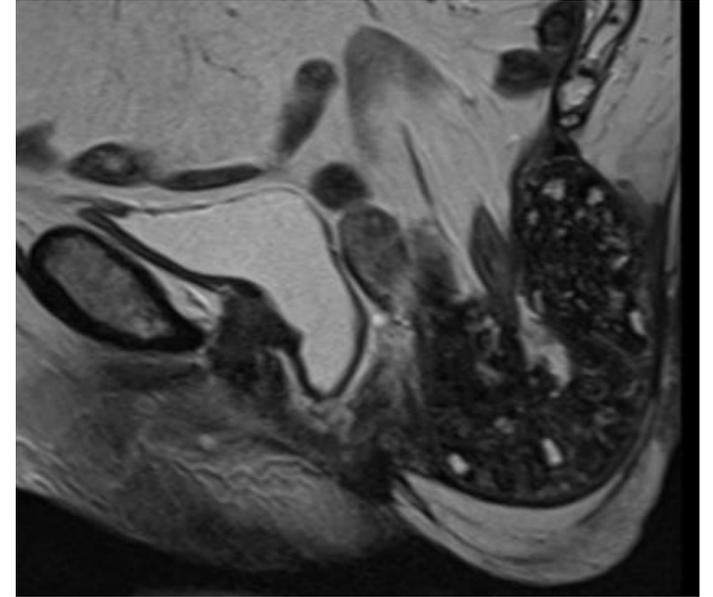
Anterior detachment



Mesh eventration

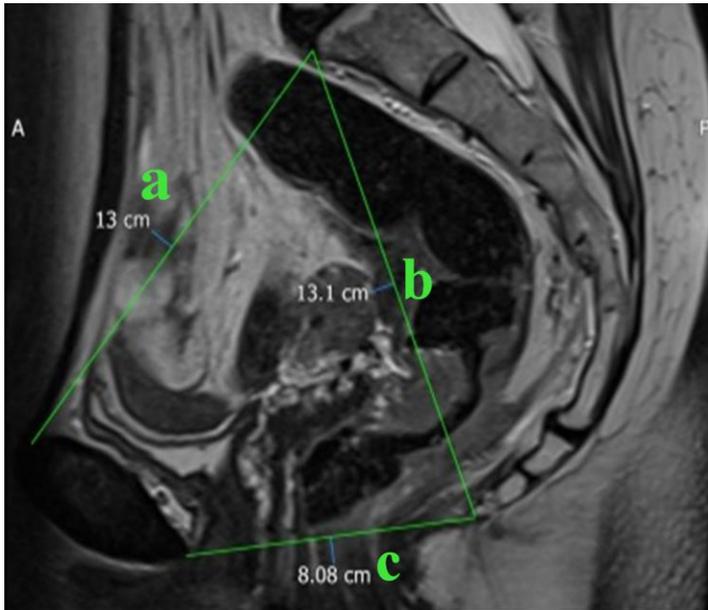


True perineal hernia



- 59 patients. Median age 68yr
- eLAPE & biomesh reconstruction
- Median 2 years MRI / CT follow up
- 17% true perineal hernia
- Median time to hernia 11 months
- >50% symptomatic

# DOES PELVIMETRY MATTER?



Characteristics of patients	True perineal hernia n=10	No perineal hernia n=49	Total patients n=59	P-Value
Age, Median (range) <sup>a</sup>	67(58-78)	68(26-79)	68(26-79)	0.69
Females, n (%) <sup>b</sup>	7(70)	14(29)	21(35)	0.03
Outlet, Mean (SD) <sup>c</sup>	9.8(1.3)	10.1(1.2)	10.1(1.2)	0.46
Inlet, Mean (SD) <sup>c</sup>	12.2(0.6)	11.9(0.9)	11.8(1.2)	0.22
Pelvic depth, Mean (SD) <sup>c</sup>	12.8(0.5)	12.8(1.3)	12.8(0.9)	0.99
Coccyx removal, n (%) <sup>b</sup>	3(30)	18(36)	21(35)	0.99
CRT, n (%) <sup>c</sup>	5(50)	29(58)	34(57)	0.68
Laparoscopic surgery, n (%) <sup>b</sup>	6(60)	13(26)	18(30)	0.06

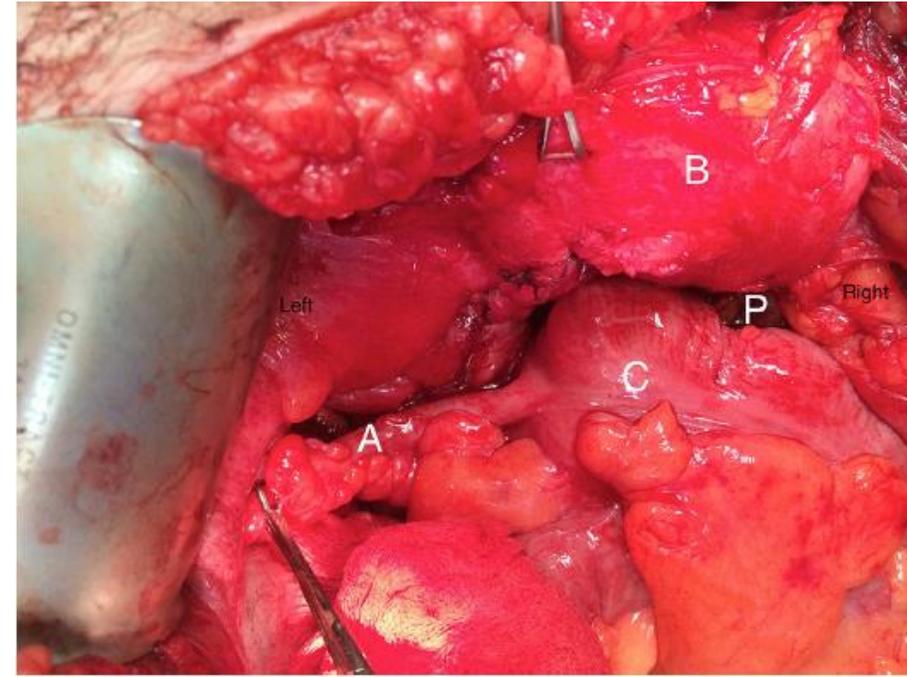
- 59 patients. Median age 68yr
- elAPE & biomesh reconstruction
- Median 2 years MRI / CT follow up
- Not on mid-sagittal scans
- Only female sex significant
- Coronal / axial?

# ANECDOTAL ADJUNCTS



- Retroverted uterus fills pelvis
- Post-menopausal women
- Dyspareunia

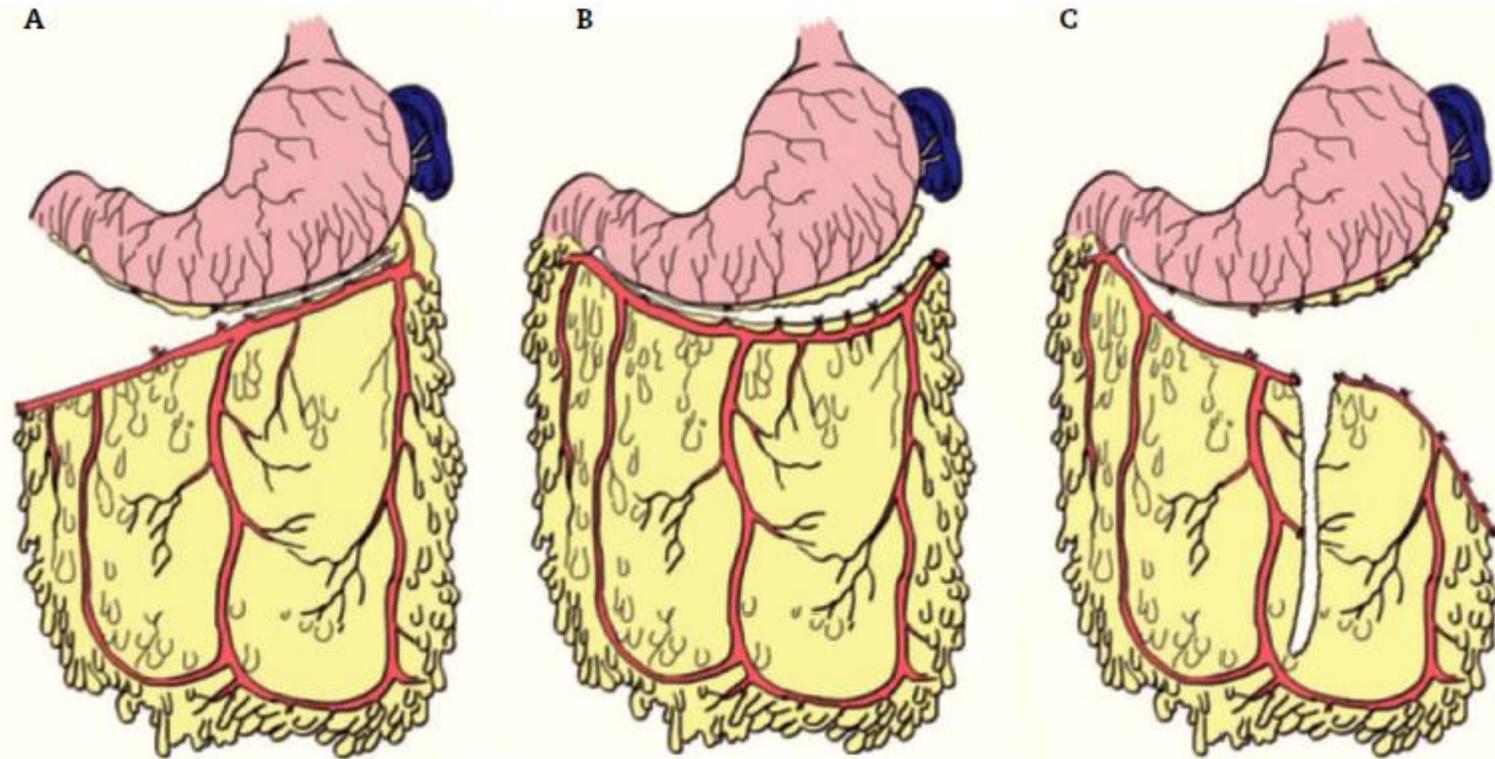
Habib DCR 2013



- Caecal mobilisation
- +/- cuff of peritoneum
- Covers pelvic inlet

Habib TCOL 2014

# OMENTOPLASTY



- Left or Right GEA
- Common in open surgery
- Frequency in laparoscopy?

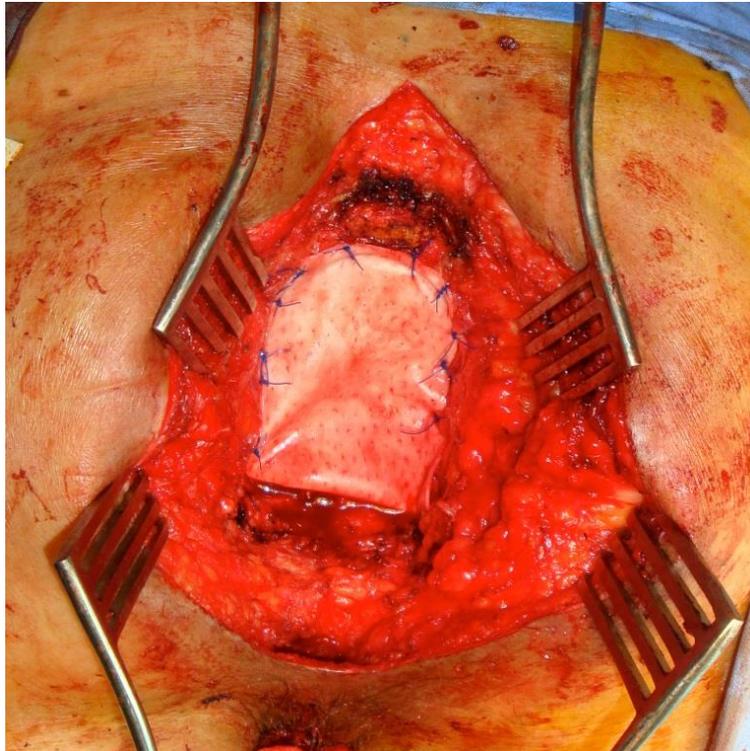
- Impact on perineal wound:
  - Improved primary healing
  - Reduced complications
  - Perineal hernia?

# PRIMARY CLOSURE

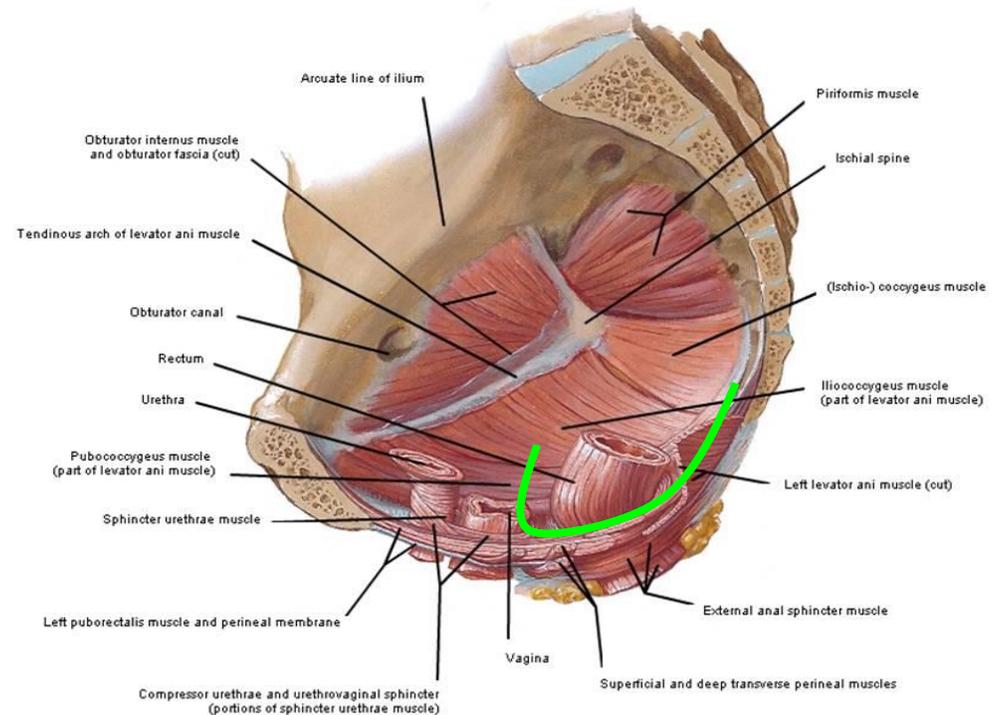
- Complication rates 10 – 80%, heterogeneous, includes anal SCC
- 160 “standard” APE, wound complication rates (Bullard et al. DCR 2005):
  - overall 41%
  - No radiotherapy 23%
  - Pre-op radiotherapy 47%
- Advocated by some, even for ELAPE
  - wound healing complications 18%
  - perineal hernia 1%



# MESH RECONSTRUCTION



- Mesh across perineal defect
- Theory – prevent small bowel pressure on perineal tissues



- Sutures
  - Presacral fascia posteriorly
  - Cut edge of levators laterally
  - Don't suture to prostate!
- Reflection of mesh anteriorly

# IDEAL FRAMEWORK

	1 Idea	2a Development	2b Exploration	3 Assessment	4 Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Single digit; highly selected	Few; selected	Many; may expand to mixed; broadening indication	Many; expanded indications (well defined)	All eligible
Number and types of surgeons	Very few; innovators	Few; innovators and some early adopters	Many; innovators, early adopters, early majority	Many; early majority	All eligible
Output	Description	Description	Measurement; comparison	Comparison; complete information for non-RCT participants	Description; audit, regional variation; quality assurance; risk adjustment
Intervention	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method	Structured case reports	Prospective development studies	Research database; explanatory or feasibility RCT (efficacy trial); disease based (diagnostic)	RCT with or without additions/modifications; alternative designs	Registry; routine database (eg, SCOAP, STS, NSQIP); rare-case reports
Outcomes	Proof of concept; technical achievement; disasters; dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes	Clinical outcomes (specific and graded); middle-term and long-term outcomes; patient-centred (reported) outcomes; cost-effectiveness	Rare events; long-term outcomes; quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No
Examples	NOTES video <sup>6</sup>	Tissue engineered vessels <sup>7</sup>	Italian D2 gastrectomy study <sup>8</sup>	Swedish obese patients study <sup>9</sup>	UK national adult cardiac surgical database <sup>10</sup>

RCT=randomised controlled trial. SCOAP=Surgical Clinical Outcomes Assessment Programme. STS=Society of Thoracic Surgeons. NSQIP=National Surgical Quality Improvement Program. NOTES=natural orifice transluminal endoscopic surgery.

**Table: Stages of surgical innovation**

## The IDEAL Reporting Guidelines

*A Delphi Consensus Statement Stage specific recommendations for reporting the evaluation of surgical innovation*

Nicole A. Bilbro, MD, MPH,\*† Allison Hirst, MSc,\* Arsenio Paez, PT, DPT,‡§ Baptiste Vasey,\* Maria Pufulete,¶ Art Sedrakyan, MD, PhD,|| and Peter McCulloch, MD\*✉, On behalf of the IDEAL Collaboration Reporting Guidelines Working Group

## A core Outcome Set for Seamless, Standardized Evaluation of Innovative Surgical Procedures and Devices (COHESIVE)

A Patient and Professional Stakeholder consensus Study



# IDEAL STAGE 2A – BIOLOGIC MESH

## Perineal Wound Complications After Extralevator Abdominoperineal Excision for Low Rectal Cancer

Jia Gang Han, M.D. • Zhen Jun Wang, M.D. • Zhi Gang Gao, M.D.  
Guang Hui Wei, M.D. • Yong Yang, M.D. • Zhi Wei Zhai, M.D.  
Bao Cheng Zhao, M.D. • Bing Qiang Yi, M.D.

Dis Colon Rectum 2019; 62: 1477–1484  
DOI: 10.1097/DCR.0000000000001495

**TABLE 4.** Multiple logistic regression analyses of potential predictors of perineal procedure-related complications in ELAPE patients

<i>Variables</i>	<i>OR (95% CI)</i>	<i>p</i>
BMI, kg/m <sup>2</sup>	1.103 (0.976–1.246)	0.12
Preoperative radiotherapy (radiotherapy vs nonradiotherapy)	22.125 (9.201–53.204)	<0.001
Total operative time, min	1.002 (0.995–1.009)	0.66
Coccygectomy (coccygectomy vs noncoccygectomy)	1.621 (0.799–3.286)	0.18
Intraoperative blood loss, mL	1.002 (1.000–1.005)	0.08
Biologic mesh reconstruction (primary closure vs mesh)	0.113 (0.043–0.294)	<0.001
Intraoperative bowel perforation (perforation vs nonperforation)	16.514 (3.136–86.959)	0.001

Perineal complications are chronic perineal pain, sexual dysfunction urinary retention, and perineal wound complications.

ELAPE, extralevator abdominoperineal excision.

# IDEAL STAGE 2A – BIOLOGIC MESH

## Original Paper

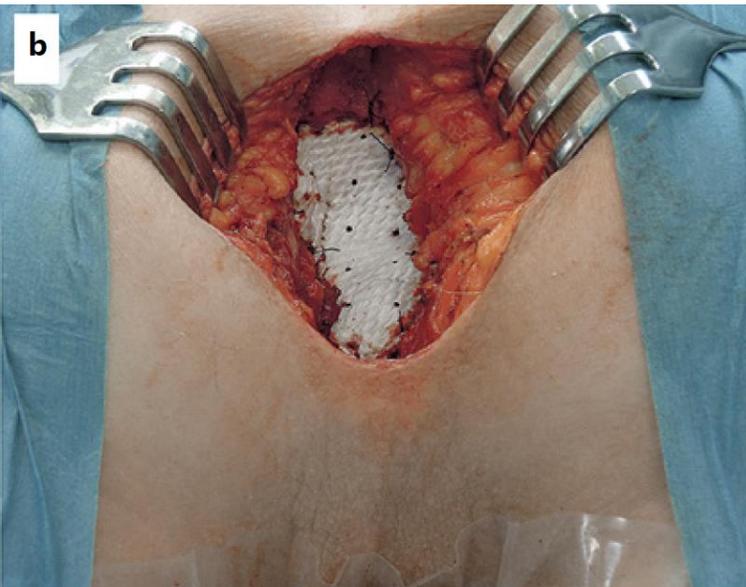
Dig Surg 2019;36:281–288  
DOI: 10.1159/000489134

Received: June 25, 2017  
Accepted: April 10, 2018  
Published online: May 15, 2018

**Digestive  
Surgery**

### Perineal Wound Closure Using Biological Mesh Following Extralevator Abdominoperineal Excision

Naseer Baloch<sup>a,b</sup> Per J. Nilsson<sup>a,b</sup> Caroline Nordenvall<sup>a,b</sup>  
Mirna Abraham-Nordling<sup>a,b</sup>



	Healed after 3 months, <i>n</i> (%)	Unhealed after 3 months, <i>n</i> (%)	<i>p</i> value <sup>a</sup>
All	58 (65.9)	30 (34.1)	
Gender			0.808
Male	42 (66.7)	21 (33.3)	
Female	16 (64.0)	9 (36.0)	
Diabetes mellitus			0.084
No	54 (69.2)	24 (30.8)	
Yes	4 (40.0)	6 (60.0)	
Smoker			0.133
No	51 (69.9)	22 (30.1)	
Yes	7 (46.7)	8 (53.3)	
Omental flap			0.488
No	20 (60.6)	13 (39.4)	
Yes	38 (69.1)	17 (30.9)	
Multiorgan resection			0.424
No	47 (68.1)	22 (31.9)	
Yes	11 (57.9)	8 (42.1)	
Type of mesh			0.265
Non-cross linked	33 (71.1)	13 (28.3)	
Cross linked	25 (59.5)	17 (40.5)	
Age, years, median (range)	68 (40–85)	65 (32–86)	0.930
Albumin value, g/L, median (range)	36 (22–41)	36 (21–45)	0.801
Duration of surgery, min, median (range)	411 (300–698)	416 (320–691)	0.822
Bleeding, mL, median (range)	525 (10–16,800)	650 (200–5,000)	0.117

# IDEAL STAGE 2A – BIOLOGIC MESH

Long-term outcomes of biological mesh repair following extra levator abdominoperineal excision of the rectum: an observational study of 100 patients

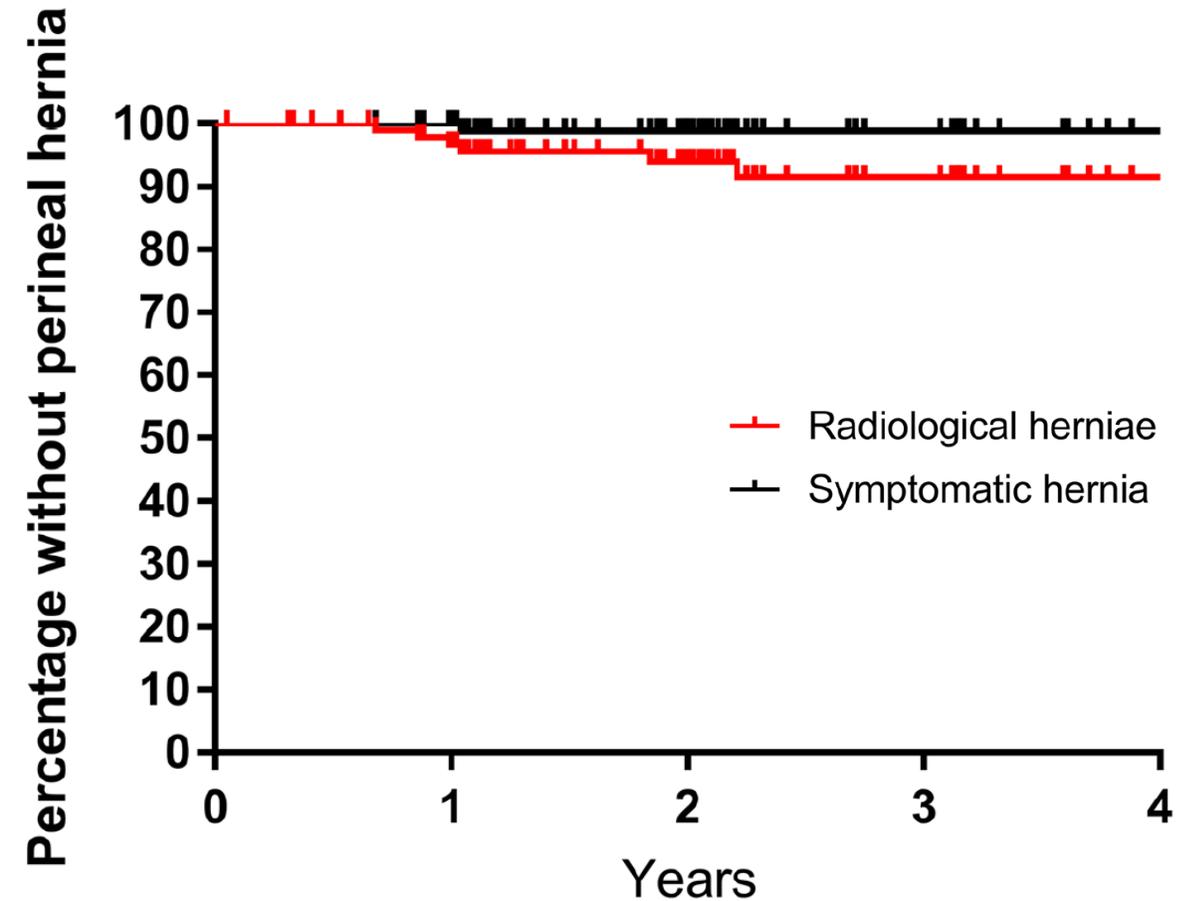
Techniques in Coloproctology (2019) 23:761–767

P. W. Thomas<sup>1</sup> · J. E. M. Blackwell<sup>1</sup> · P. J. J. Herrod<sup>1,3</sup> · O. Peacock<sup>1</sup> · R. Singh<sup>2</sup> · J. P. Williams<sup>1,3</sup> · N. G. Hurst<sup>1</sup> · W. J. Speake<sup>1</sup> · A. Bhalla<sup>1</sup> · J. N. Lund<sup>1,3</sup>

**Table 3** Wound Complications

Wound complication	Number of patients, <i>N</i> (%)	Clavien–Dindo classification
Delayed wound healing	33 (33%)	I
Simple discharge requiring dressing	8 (8%)	I
Sinus formation	5 (5%)	I
Partial dehiscence	4 (4%)	I
Superficial wound infection requiring antibiotics	9 (9%)	II
Dehiscence requiring EUA	3 (3%)	IIIb
Collection/abscess requiring VAC	4 (4%)	IIIb

*EUA* examination under anaesthesia, *VAC* vacuum assisted closure



# 2B - LOREC APE REGISTRY

- UK observational registry
- 2012 - 2014
- 42 units
- 266 patients
- Descriptive
- Perineal hernia not reported

	ELAPE	Non-ELAPE
Primary closure – no mesh	26 (15%)	51 (54%)
Primary closure with mesh	95 (55%)	27 (29%)
Mesh closure	113 (66%)	31 (33%)
- Biological	102 (90%)	14 (45%)
- Vicryl	7 (6%)	6 (19%)
- Polyester	0	10 (32%)
- Prolene	1 (1%)	0
- Composite	3 (3%)	1 (3%)
Flap closure	36 (21%)	5 (5%)
- VRAM	14 (8%)	3 (3%)
- Local myo-cutaneous	10 (6%)	2 (2%)
- Fascio-cutaneous	12 (7%)	0
Plastics involved	24 (14%)	4 (4%)
Flap plus mesh	9	2

# 2B - DANISH NATIONAL REGISTRY

**TABLE 2.** Demographic and tumor-specific variables according to type of surgery

Variable	ELAPE (N = 245)	Conventional APE (N = 200)	p
Closure			
Suture	44 (18)	156 (78)	<0.001
Biological mesh	165 (67)	42 (21)	
Other mesh	20 (8)	1 (0.5)	
Flap closure	15 (6)	1 (0.5)	
Other	1 (1)	0 (0)	
Wound complications, y/n, n (%)	107/138 (44/56)	51/149 (25/75)	<0.001
Pain, y/n, n (%)	94/151 (38/62)	43/157 (21/79)	<0.001
Hernia, y/n, n (%)	4/240 (2/98)	5/195 (2/98)	0.74

- 2009 – 2012
- 445 patients
- National registry / observational
- Perineal hernia – clinical and CT

- eLAPE vs conventional:
  - ↑T3 & T4
  - eLAPE ↑ CRT
  - Colorectal > general surgeon
  - Younger, less co-morbid

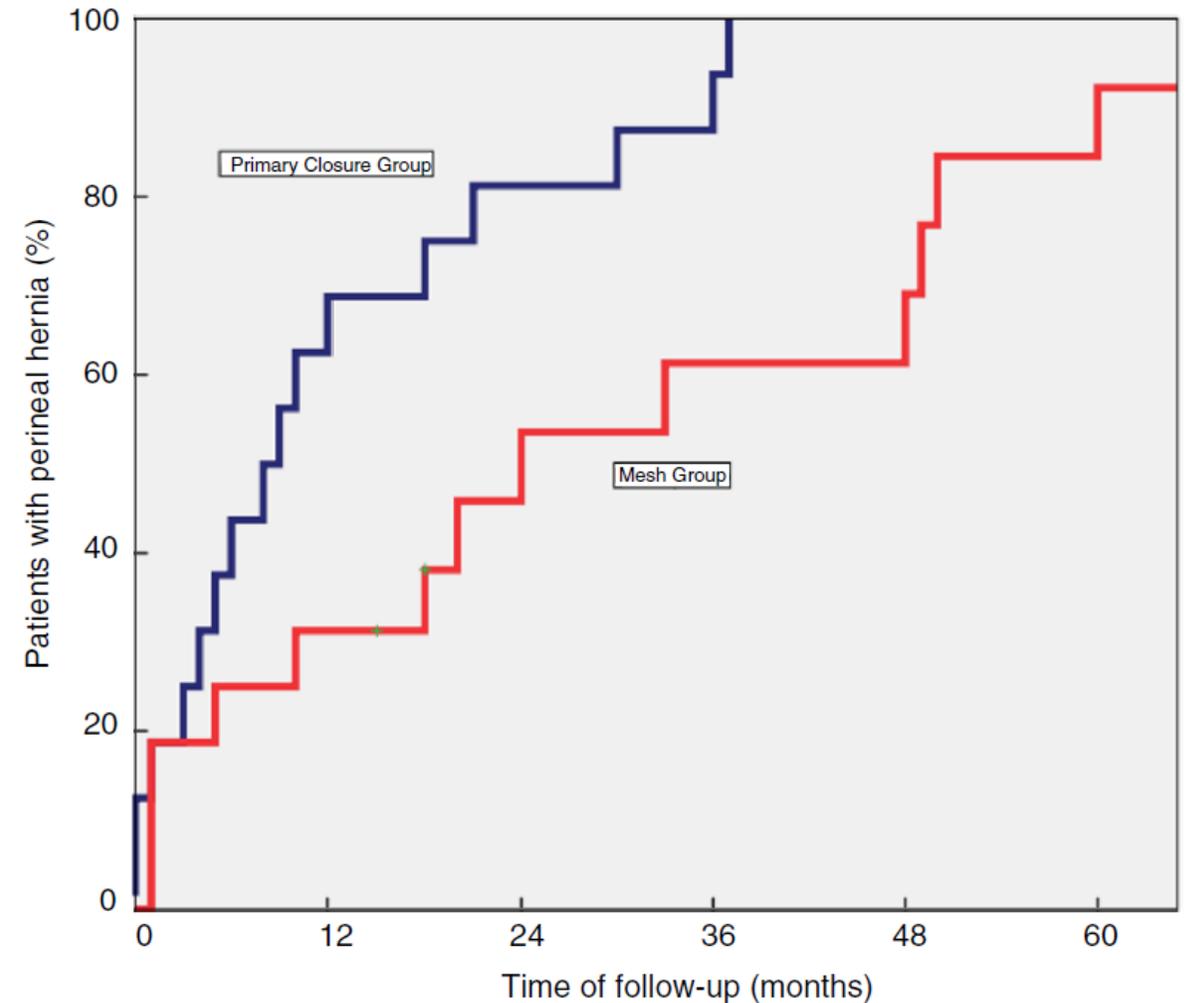
# 2B - SPANISH COLLECTIVE

Biological mesh reconstruction versus primary closure for preventing perineal morbidity after extralevator abdominoperineal excision: a multicentre retrospective study

J. Sancho-Muriel\* , J. Ocaña† , H. Cholewa\*, J. Nuñez†, P. Muñoz†, B. Flor\*, J. C. García†, E. García-Granero\*, J. Die† and M. Frasson\* 

**Table 3** Perineal wound morbidity.

	Perineal wound morbidity		P-value OR (CI 95%)
	No n (%)	Yes n (%)	
Perineal wound closure			
Prophylactic mesh	36 (45)	44 (55)	0.01 OR: 2.38 (1.18-4.78)
Primary closure	39 (66.1)	20 (33.9)	



Primary Closure median (CI95%): 8 months (2.1-13.8); Prophylactic Mesh median (CI95%): 24 months (7.2-40.7). Log Rank test: p < 0.01

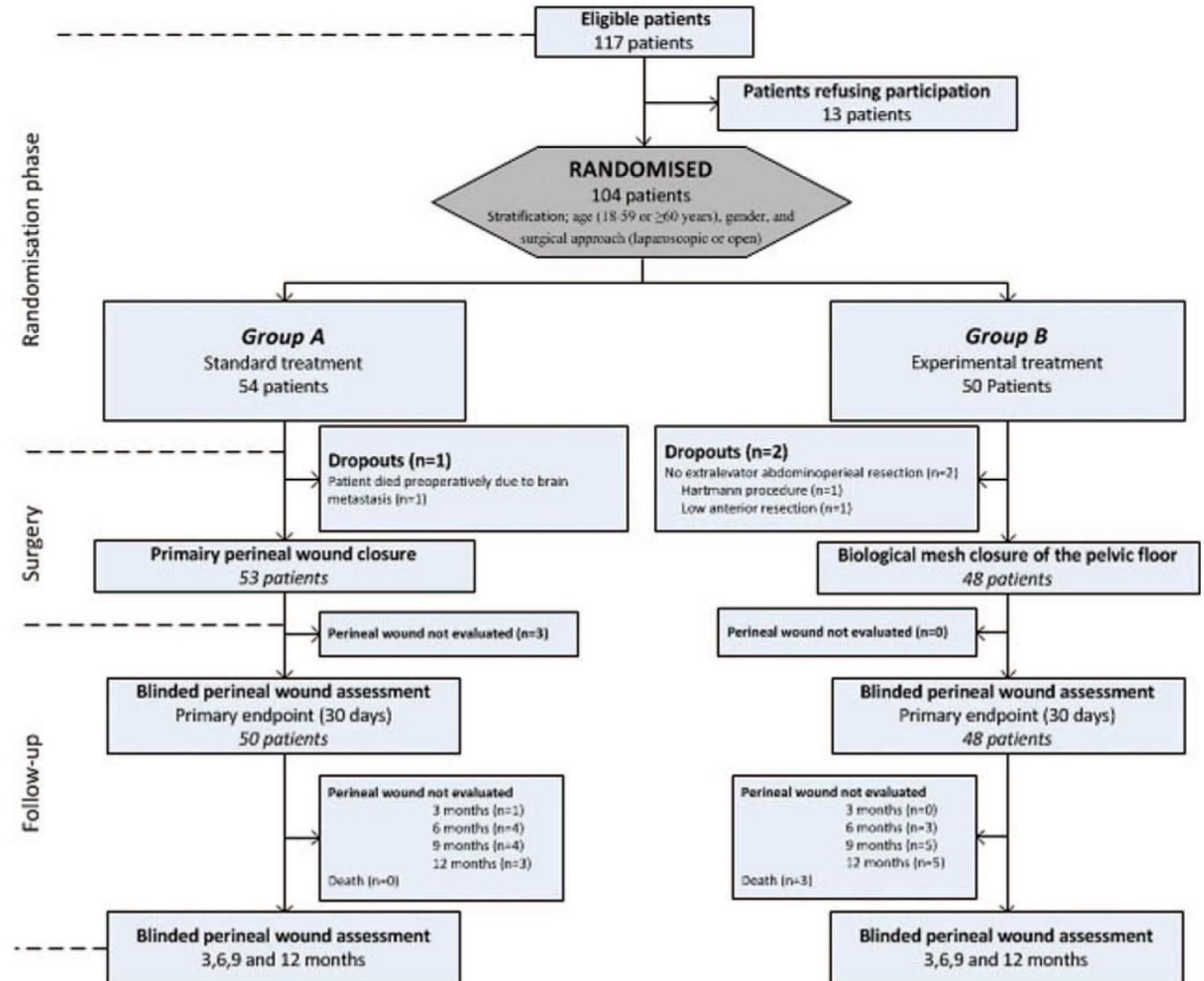
# BIOPEX – 1 YEAR

## RANDOMIZED CONTROLLED TRIAL

Biological Mesh Closure of the Pelvic Floor After Extralevator Abdominoperineal Resection for Rectal Cancer

*A Multicenter Randomized Controlled Trial (the BIOPEX-study)*

- 104 patients, post SCRT, eIAPE
- CT @ 1 year
- RCT – primary vs biomesh
- ↓ perineal hernia



# BIOPEX – 1 YEAR

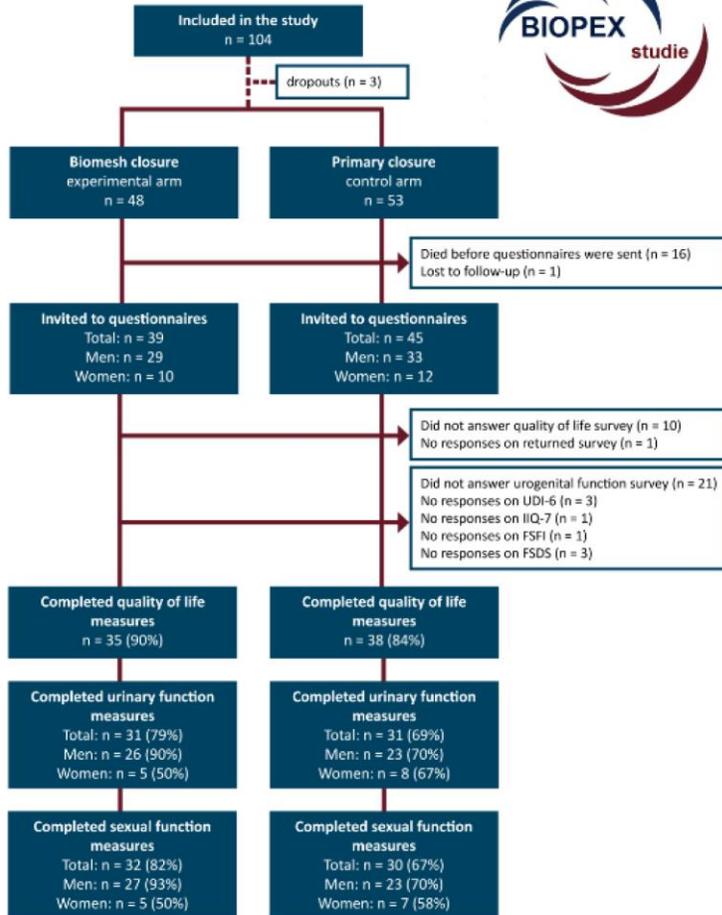
TABLE 2. Perineal Wound Healing

		Group A	Group B	
		Primary Closure	Biological Mesh Closure	<i>P</i>
		(n = 53)*	(n = 48)*	
Normal perineal wound healing (Southampton wound score <2)	7 Days postoperative (n, %)	35/50 (70)	34/47 (72)	0.7993
	30 Days postoperative (n, %)	33/50 (66)	30/48 (63)	0.7177
	3 Months postoperative (n, %)	42/52 (81)	39/48 (81)	0.9511
	6 Months postoperative (n, %)	43/49 (88)	39/45 (87)	0.8643
	9 Months postoperative (n, %)	44/49 (90)	41/43 (95)	0.4419
	12 Months postoperative (n, %)	49/50 (98)	41/43 (95)	0.5940
Severity of infection (at 30 days)	Erythema and other signs of inflammation (n, %)	0	2/48 (4)	0.2373
	Clear or hemoserous discharge (n, %)	7/50 (14)	9/48 (19)	0.5916
	Pus discharge (n, %)	7/50 (14)	2/48 (4)	0.1599
	Deep or severe wound infection (n, %)	3/50 (6)	5/48 (10)	0.4823
Surgical complications (within 90 days)	Overall (n, %)	20 (38)	20 (42)	0.8964
Nonsurgical complications (within 90 days)	Overall (n, %)	2 (6)	3 (6)	0.6689
Perineal hernia	Freedom from perineal hernia (%; 95% CI)	73 (61–85)	87 (77–97)	0.0316
Within 12 months	Asymptomatic perineal hernia (n, %)	4 (8)	2 (4)	
Surgical reinterventions	Total (n, %)	5 (10)	3 (6)	0.7169
For perineal wound problems within 12 months	Perineal hernia correction (n, %)	2 (4)	1 (2)	
	Abscess drainage (n, %)	1 (2)	2 (4)	
	Gluteus flap (n, %)	2 (4)	0	
Percutaneous reintervention	Abscess drainage (n, %)	1 (2)	3 (6)	0.3480
For perineal wound problems within 12 months				

Surgical complications are urinary retention, ileus, trocar hernia, postoperative bleeding, presacral fistula, stoma dysfunction, pneumonia, perineal hernia <90 days, (appendix). Nonsurgical complications are; atrial fibrillation, heart decompensation, urinary tract infection, cholecystitis, the flu (appendix).

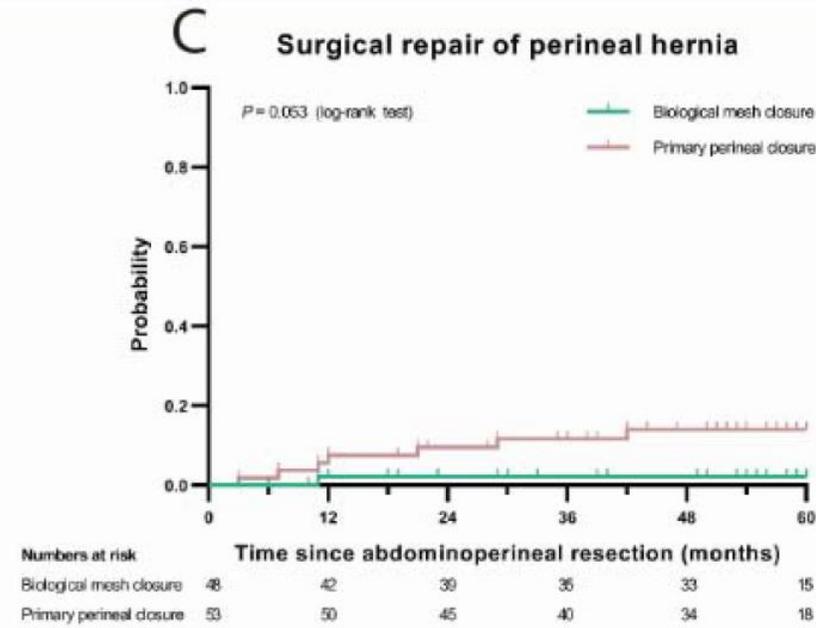
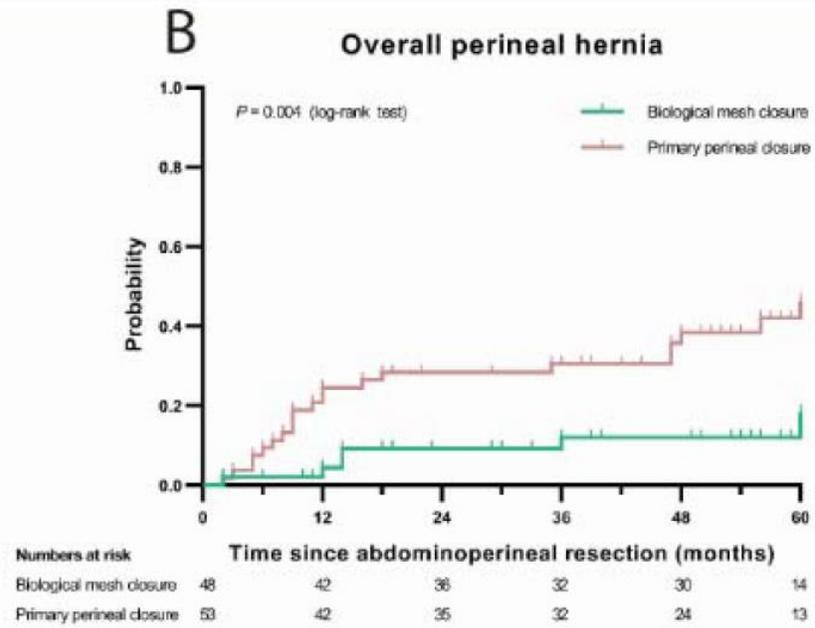
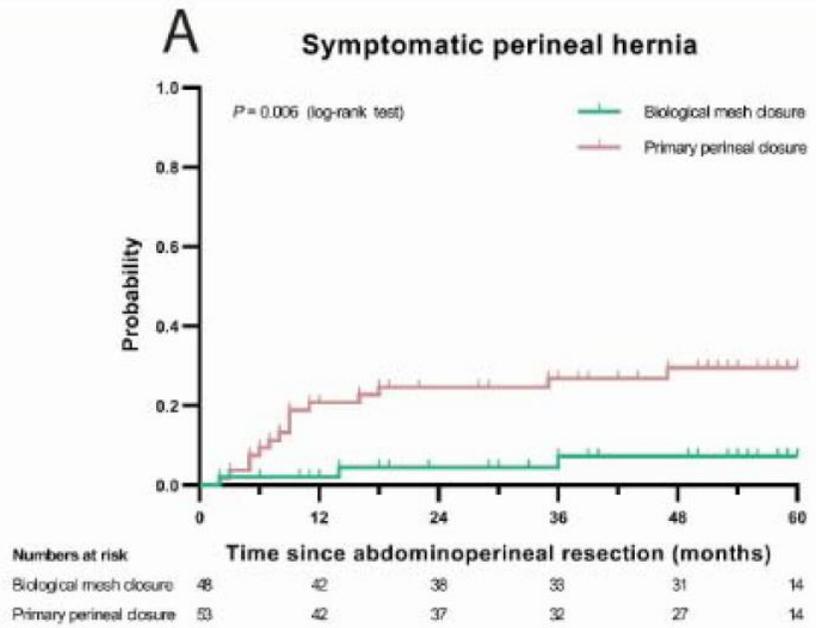
\*Number of evaluable patients for each group differs for different time intervals postoperatively (Fig. 1).

# BIOPEX – 5 YEAR



Variables		Primary Closure (n = 53)	Biological Mesh (n = 48)	P-value
<b>Follow-up duration</b>	<i>Median in years (IQR)</i>	4.8 (3.8-5.1)	4.7 (2.6-5.1)	0.380
<b>Perineal hernia</b>				
<i>Symptomatic</i>	<i>5-year actuarial rate** (95% CI)</i>	30% (10-49)	7% (0-30)	0.006
	<i>Cumulative incidence, n (%)</i>	15/53 (28)	3/48 (6)	0.004
	<i>Perceptible by clinical examination, n (%)</i>	13/15	3/3	-
	<i>Detected by radiological imaging only, n (%)</i>	2/15	0/3	-
<i>Overall*</i>	<i>5-year actuarial rate** (95% CI)</i>	51% (31-70)	24% (1-47)	0.004
	<i>Cumulative incidence, n (%)</i>	21/53 (40)	6/48 (13)	0.002
	<i>Perceptible by clinical examination, n (%)</i>	17/21	5/6	-
	<i>Detected by radiological imaging only, n (%)</i>	4/21	1/6	-
<i>Surgical repair</i>	<i>5-year actuarial rate** (95% CI)</i>	14% (0-34)	2% (0-25)	0.053
	<i>Cumulative incidence, n (%)</i>	7/53 (13)	1/48 (2)	0.062

# BIOPEX – 5 YEAR



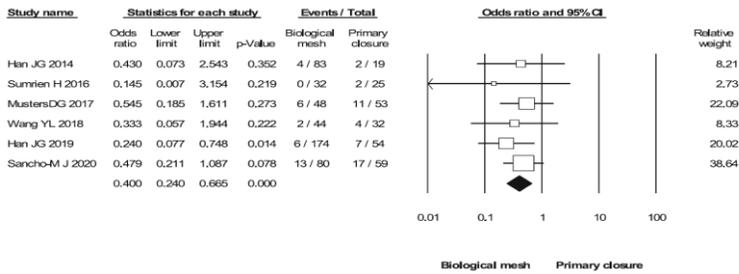
# REVIEWS

## Meta-analysis of biological mesh reconstruction versus primary perineal closure after abdominoperineal excision of rectal cancer

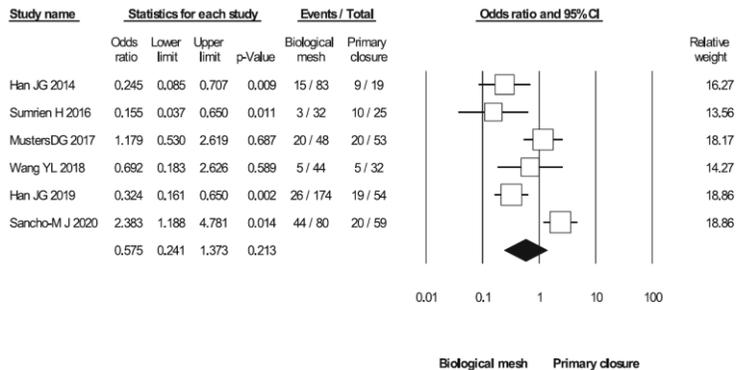
Nasir Zaheer Ahmad<sup>1</sup> · Muhammad Hasan Abbas<sup>2</sup> · Noof Mohammed A. B. Al-Naimi<sup>3</sup> · Amjad Parvaiz<sup>4,5</sup>

Accepted: 18 December 2020 / Published online: 3 January 2021

### Perineal hernia



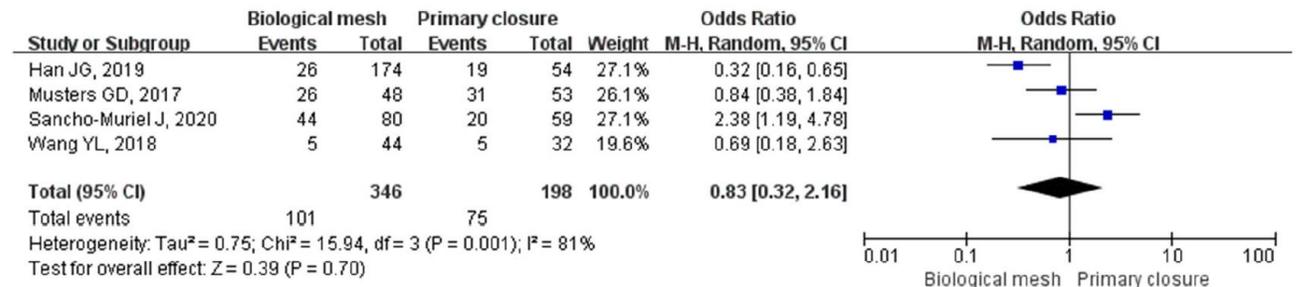
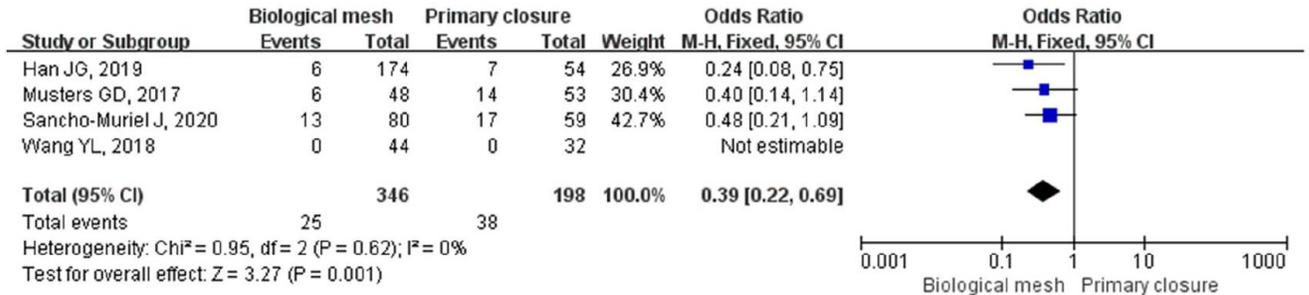
### Perineal wound complications



## Comparison of perineal morbidity between biologic mesh reconstruction and primary closure following extralevator abdominoperineal excision: a systematic review and meta-analysis

Yu Tao<sup>1</sup> · Jia Gang Han<sup>1</sup> · Zhen Jun Wang<sup>1,2</sup>

### a) Perineal hernia

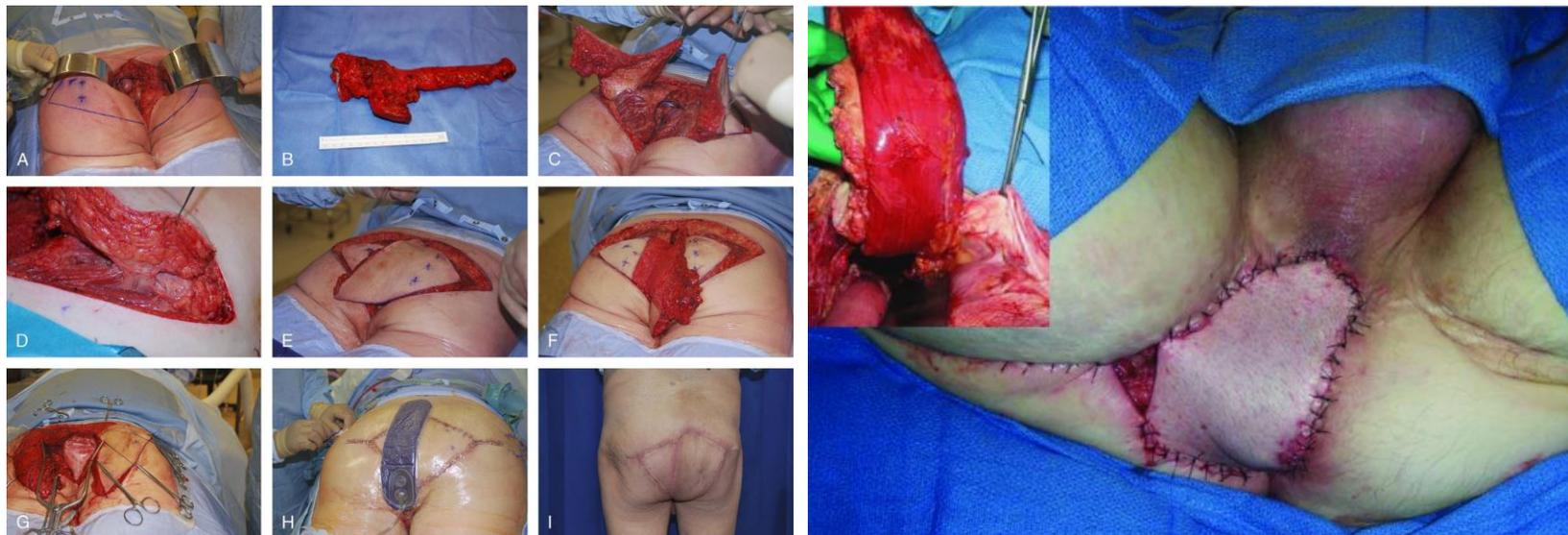


# WHICH FLAP?

DOI: 10.1097/PRS.0000000000007976

Region	Pedicle	Flaps	Results
Abdomen	Inferior epigastric artery	VRAM	31 articles
		ORAM	4 articles
		RAM	4 articles
		DIEP	1 article
Gluteal region	Superior/inferior gluteal artery	MC VY/rotation flap	6 articles
		FC VY/rotation flap	6 articles
		IGAP	2 articles
Upper thigh	Medial femoral circumflex artery	Gracilis flap	4 articles
	Lateral femoral circumflex artery	ALT ± VL	1 article
Gluteal fold/perineum	Internal pudendal artery	IPAP	2 articles
		PTO	1 article

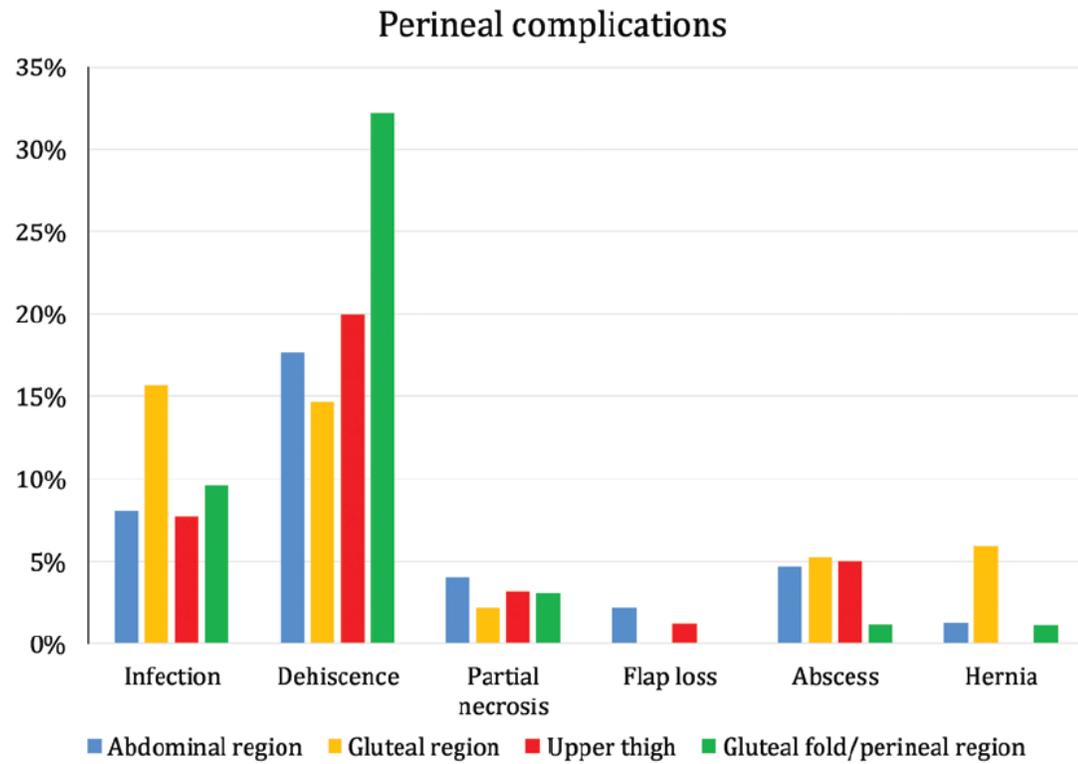
DOI: 10.1097/SAP.0000000000003258



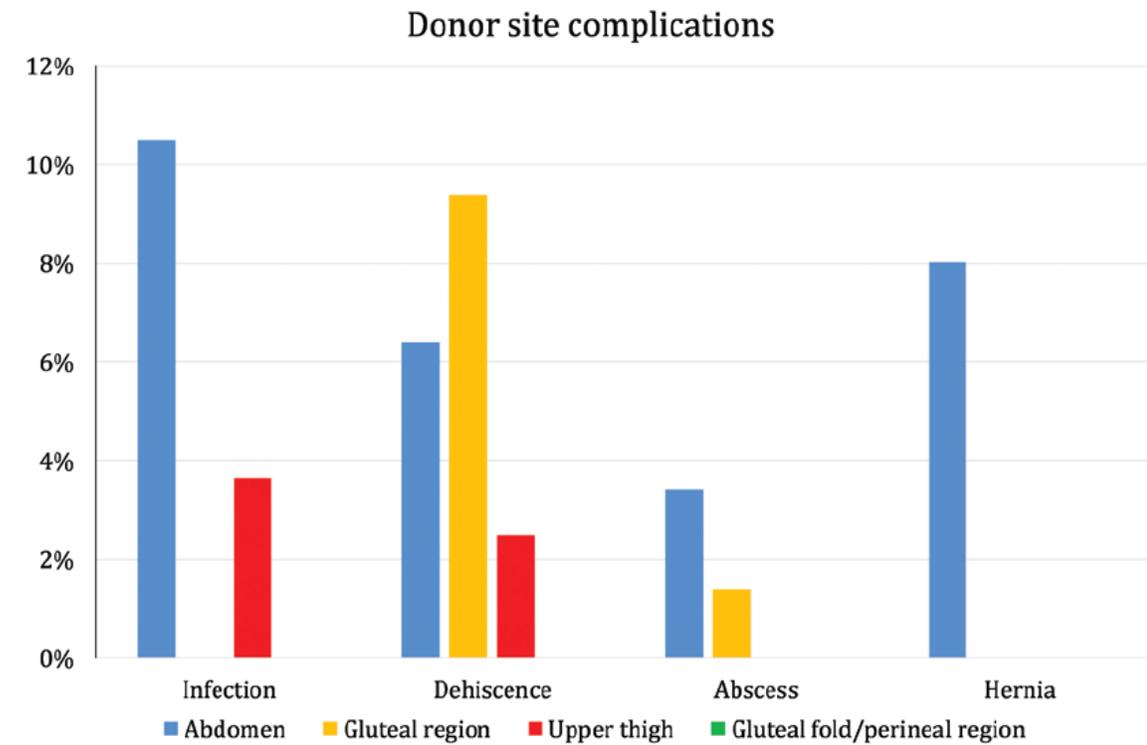
doi:10.1111/codi.14654

# WHICH FLAP?

DOI: 10.1097/PRS.00000000000007976



**Fig. 5.** Perineal complications, organized by flap group.



**Fig. 6.** Donor-site complications, organized by flap group.

# WHICH METHOD?

**Table 5** The results of tissue flap and biological mesh reconstruction of the perineum after extralevator abdominoperineal excision.

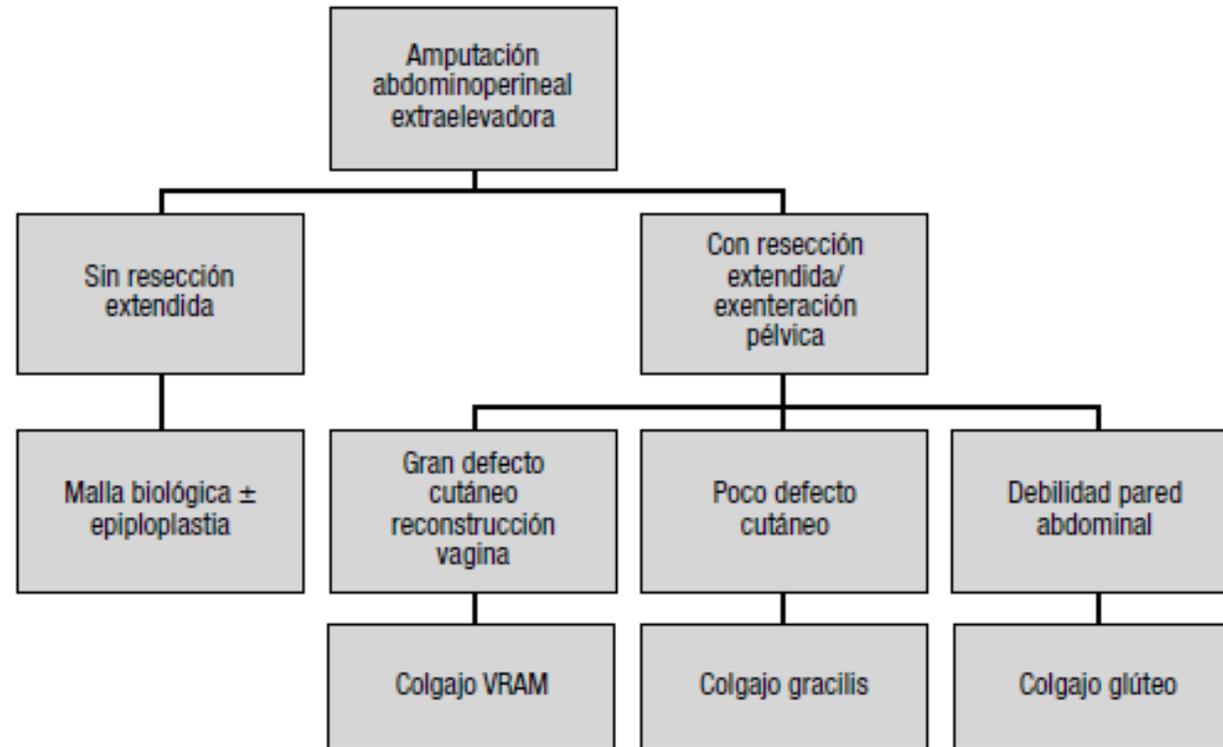
Repair	No. of pts	Average age (years)	M/F	Neoadjuvant radiotherapy	30-day mortality	Dindo I, II or III	Dindo I and II	Dindo III	Perineal hernia
Biological mesh	85	67.3	50/27 (8 NS)	51 (60%)	2 (2.4%)	24 (28.2%)	15 (17.6%)	9 (10.6%)	3 (3.5%)
Tissue flap (excluding West)	179	66.6	109/61 (9 NS)	147 of 162 (17 NS) (90.7%)	1 (0.5%)	56 (31.3%)	41 (22.9%)	15 (8.3%)	7 (3.9%)
<i>P</i> -value			1.00	< 0.0001*	0.2433	0.6686	0.4206	0.6474	1.00
Tissue flap (including West)	255				1 (0.4%)	81 (31.8%)	66 (25.9%)	15 (5.9%)	
					0.1554	0.5894	0.1423	0.1479	

NS, not stated in paper.

\*Statistically significant.

- Multiple subsequent reviews incorporating numerous single institution case series – similar results
- No clear differences

# WHICH APPROACH WHEN?



- Tailored approach
- eLAPE – biomesh
- Which biomesh? Caveat emptor!
- Extended resections – flap
- Which flap? Depends.....

# ACPGBI GUIDELINES

## Closure of the perineal defect after abdominoperineal excision for rectal adenocarcinoma – ACPGBI Position Statement

**J. D. Foster\***, **S. Tou†**, **N. J. Curtis‡§** , **N. J. Smart¶** , **A. Acheson\*\***,  
**C. Maxwell-Armstrong\*\***, **A. Watts¶**, **B. Singh††** and **N. K. Francis‡‡** 

Colorectal Disease © 2018 The Association of Coloproctology of Great Britain and Ireland. **20** (Suppl. 5), 5–23

### *Recommendations*

There is insufficient published outcome data comparing flap and mesh closure to recommend one over the other. We advocate a personalised approach to each patient when deciding upon the method of perineal wound reconstruction following ELAPE. Decisions regarding what method should be employed should include consideration of surgical expertise, morbidity, cost-effectiveness, and the size of the defect that needs to be filled.

Biologic mesh can be effectively used to close the perineal defect following ELAPE. (↑↑) There is insufficient evidence at present to recommend one particular type of mesh over another.

Reconstruction of the pelvic floor with either biologic mesh or myocutaneous flap may lead to a lower incidence of perineal hernia at one year compared with primary closure. (↑?)

# ONGOING RESEARCH

## Inclusion criteria:

- rectal adenocarcinoma / anal cancer
- Abdominoperineal resection indication
- Voluntary written informed consent
- Patients with social security insurance
- Age ≥ 18
- ECOG performance status 0-2

Patient programmed for abdominoperineal resection:

## Exclusion criteria

- Indication to do a reconstruction by a musculocutaneous flap
- Metastasis disease deemed non-resectable with curative intent
- Immunosuppressive drugs treatment
- Uncontrolled diabetes
- Patient under juridical protection

Randomization  
n=140

Primary closure group  
Control group

Mesh assisted closure group  
Experimental group

Post operative  
Perineal healing  
Single blinded

Post operative  
Perineal healing  
Single blinded

- Follow up : 1, 3, 6, 9, 12 month
- Cost utility analysis
  - Perineal wound healing
  - Quality of life

**Randomised clinical trial for the cost-utility evaluation of two strategies of perineal reconstruction after abdominoperineal resection in the context of anorectal carcinoma: biological mesh repair versus primary perineal wound closure, study protocol for the GRECCAR 9 Study**

Etienne Buscail<sup>1,2</sup>, Cindy Canivet,<sup>3</sup> Laurent Ghouti,<sup>1</sup> Sylvain Kirzin,<sup>4</sup> Nicolas Carrere,<sup>1</sup> Laurent Molinier,<sup>5</sup> Aline Rosillo,<sup>6</sup> Valerie Lauwers-Cances,<sup>7</sup> Nadège Costa,<sup>5</sup> French Research Group of Rectal Cancer Surgery (GRECCAR Group)

**Table 1** Southampton Wound Assessment Scale

Grade	Definition
0	Normal healing
I	Normal healing with mild bruising or haematoma
II	Erythema plus other signs of inflammation
III	Clear or haemoserous discharge
IV	Pus
V	Deep or severe wound infection with or without tissue breakdown; haematoma requiring aspiration

STUDY PROTOCOL

Open Access

## Perineal wound closure using gluteal turnover flap or primary closure after abdominoperineal resection for rectal cancer: study protocol of a randomised controlled multicentre trial (BIOPEX-2 study)



Sarah Sharabiany<sup>1\*</sup>, Robin D. Blok<sup>1,2</sup>, Oren Lapid<sup>3</sup>, Roel Hompes<sup>1</sup>, Wilhelmus A. Bemelman<sup>1</sup>, Victor P. Alberts<sup>1</sup>, Bas Lammé<sup>4</sup>, Jan H. Wijsman<sup>5</sup>, Jurriaan B. Tuynman<sup>6</sup>, Arend G. J. Aalbers<sup>7</sup>, Geerard L. Beets<sup>7</sup>, Hans F. J. Fabry<sup>8</sup>, Ivan M. Cherepanin<sup>9</sup>, Fatih Polat<sup>9</sup>, Jacobus W. A. Burger<sup>10</sup>, Harm J. T. Rutten<sup>10,11</sup>, Robert J. I. Bosker<sup>12</sup>, Koen Talsma<sup>12</sup>, Joost Rothbarth<sup>13</sup>, Cees Verhoeve<sup>13</sup>, Anthony W. H. van de Ven<sup>14</sup>, Jarmila D. W. van der Bilt<sup>14</sup>, Eelco J. R. de Graaf<sup>15</sup>, Pascal G. Doormeboosch<sup>15</sup>, Jeroen W. A. Leijtens<sup>16</sup>, Jeroen Heemsker<sup>16</sup>, Baljit Singh<sup>17</sup>, Sanjay Chaudhri<sup>17</sup>, Michael F. Gerhards<sup>18</sup>, Tom M. Karsten<sup>18</sup>, Johannes H. W. de Wilt<sup>19</sup>, Andre J. A. Bremers<sup>19</sup>, Ronald J. C. L. M. Vuytsteke<sup>20</sup>, Gijsbert Heuff<sup>20</sup>, Anna A. W. van Geloven<sup>21</sup>, Pieter J. Tanis<sup>1</sup> and Gijsbert D. Musters<sup>1</sup>

### Abstract

**Background:** Abdominoperineal resection (APR) for rectal cancer is associated with high morbidity of the perineal wound, and controversy exists about the optimal closure technique. Primary perineal wound closure is still the standard of care in the Netherlands. Biological mesh closure did not improve wound healing in our previous randomised controlled trial (BIOPEX-study). It is suggested, based on meta-analysis of cohort studies, that filling of the perineal defect with well-vascularised tissue improves perineal wound healing. A gluteal turnover flap seems to be a promising method for this purpose, and with the advantage of not having a donor site scar. The aim of this study is to investigate whether a gluteal turnover flap improves the uncomplicated perineal wound healing after APR for rectal cancer.

(Continued on next page)

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Open access

Protocol

## BMJ Open Multicentre, randomised trial comparing acellular porcine collagen implant versus gluteus maximus myocutaneous flap for reconstruction of the pelvic floor after extended abdominoperineal excision of rectum: study protocol for the Nordic Extended Abdominoperineal Excision (NEAPE) study

Martin Rutegård,<sup>1,2</sup> Jörgen Rutegård,<sup>1</sup> Markku M Haapamäki<sup>1</sup>

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### ABSTRACT

**Introduction** Different surgical techniques are used to cover the defect in the floor of the lesser pelvis after an 'extrelevator' or 'extended' abdominoperineal excision for advanced rectal cancer. However, these operations are potentially mutilating, and the reconstruction method of the pelvic floor has been studied only sparsely. We aim to study whether a porcine-collagen implant is superior or equally beneficial to a gluteus maximus myocutaneous flap as a reconstruction method.

**Methods and analysis** This is a multicentre non-blinded randomised controlled trial with the experimental arm using a porcine-collagen implant and the control arm using a gluteus maximus muscle and skin rotation flap. Considered for inclusion are patients with rectal cancer, who are operated on with a wide abdominoperineal rectal excision including most of the levator muscles and where the muscle remnants cannot be closed in the midline with sutures. Patients with a primary or recurrent rectal cancer with an estimated survival of more than a year are eligible. The randomisation is computer generated with a concealed sequence and stratified by participating hospital and preoperative radiotherapy regimen. The main outcome is physical performance 6 months after surgery measured with the timed-stands test. Secondary outcomes are perineal wound healing, surgical complications, quality of life, ability to sit and other outcomes measured at 3, 6 and 12 months after surgery. To be able to state experimental arm non-inferiority with a 10% margin of the primary outcome with 90% statistical power and assuming 10% attrition, we aim to enrol 85 patients from May 2011 onwards.

**Ethics and dissemination** The study has been approved by the Regional Ethical Review board at Umeå University (protocol no: NEAPE-2010-335-31M). The results will

### Strengths and limitations of this study

- This is the first head-to-head comparison of an acellular porcine-collagen implant versus a gluteus maximus myocutaneous flap to reconstruct the defect in the lesser pelvis after extended abdominoperineal resection.
- This is a randomised controlled trial, thus ensuring minimal confounding.
- The primary outcome of physical performance is objectively measured, clinically relevant and important to patient and physician alike.
- The trial intervention is however impossible to blind, which might introduce bias.
- The planned sample size is adequate to evaluate non-inferiority of the implant arm concerning physical performance, but might be inadequate for secondary and subgroup analyses.

be disseminated through patient associations and conventional scientific channels.  
**Trial registration number** NCT01347697; Pre-results.

### INTRODUCTION

#### Background and rationale

Abdominoperineal excision (APE) of the rectum is a common procedure for rectal carcinomas situated too low for sphincter-saving surgery, especially if the levator and sphincter musculature is infiltrated.<sup>1</sup> The local recurrence rate after APE has been reported to be from 5% to 47%.<sup>2,3</sup> Consequently, much

# SUMMARY

- Perineal morbidity after ELAPE is common
- Some evidence to support biologic mesh use to prevent perineal hernia
- Limited comparative evidence on optimal flap choice
- Optimal technique for perineal reconstruction unknown

