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Società Italiana di Chirurgia



Patologia Traumatica Del Perineo

Massimo Mongardini, Federico Maria Mongardini, Menelaos Karpathiotakis



Traumi Chiusi *solitamente in conseguenza di traumatologia della strada o di natura accidentale (infortuni sul lavoro, precipitazioni o cadute dall'alto, traumatologia varia)*

Parto *per sproporzione cefalo-pelvica fino ad arrivare a lacerazioni della vagina e del corpo perineale o per una episiotomia mal condotta o complicata (ematomi o sepsi) con conseguente interruzione degli sfinteri, del retto e del canale anale;*

Corpi estranei ingeriti *specialmente se acuminati, ingeriti volontariamente a scopo autolesivo o accidentalmente (ossa, lisca di pesce, frammenti di vetro, protesi odontoiatriche) raggiungendo il retto possono rimanere ancorati e portare alla perforazione del viscere e/o alla sepsi*

Corpi estranei introdotti dall'ano

Violenza sessuale

Lesioni pneumatiche *fino ad arrivare all'esplosione del retto o dell'intero intestino crasso (aria compressa introdotta attraverso l'ano)*

Lesioni iatrogene *da chirurgia coloretale, ginecologica, urologica e pelvi-perineale*

Lesioni penetranti *(da arma da fuoco o da taglio)*

Lesioni da impalamento

La **Strategia di trattamento** delle
lesioni perineali è strettamente collegata alle

caratteristiche cliniche
posizione
durata del danno
estensione esatta del danno.



La **Maggioranza delle lesioni**
spesso sono

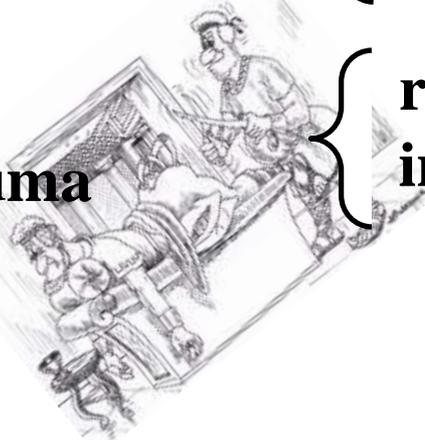
limitate al retto e alla vagina
responsabili di traumi minori

(presenza di corpi estranei o di pratiche omo-eterosessuali o di traumi contusivi chiusi) che non richiedono particolari ricostruzioni o diversioni del transito fecale.



Nei **Casi complessi**
o nel contesto di un **politrauma**

ricostruzioni complesse e
interventi chirurgici seriati

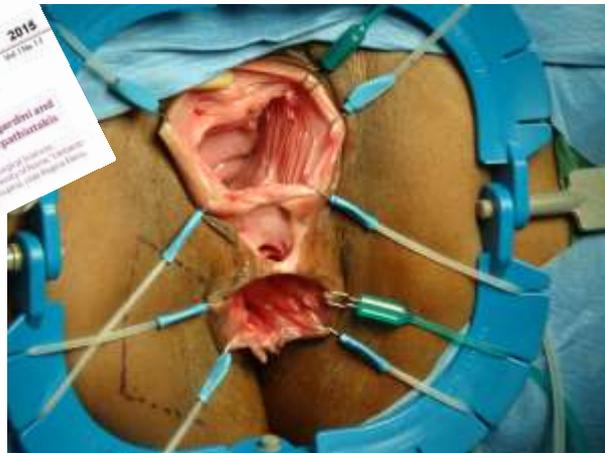




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Le lesioni osservate con **maggiore frequenza** nella nostra esperienza sono sicuramente legate ai **traumi ostetrici** o ad esiti di **interventi chirurgici proctologici**.



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Le lesioni osservate con minor frequenza ma che spesso richiedono una dose di eclettismo chirurgico riguardano corpi estranei (*ingeriti o introdotti*), **violenza sessuale, traumatismi vari** (*impalamento, strada, pneumatiche, ecc.*)

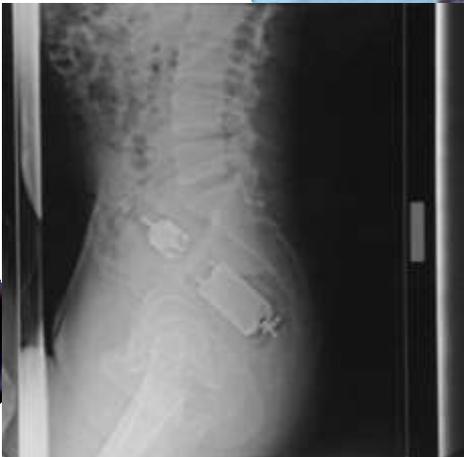
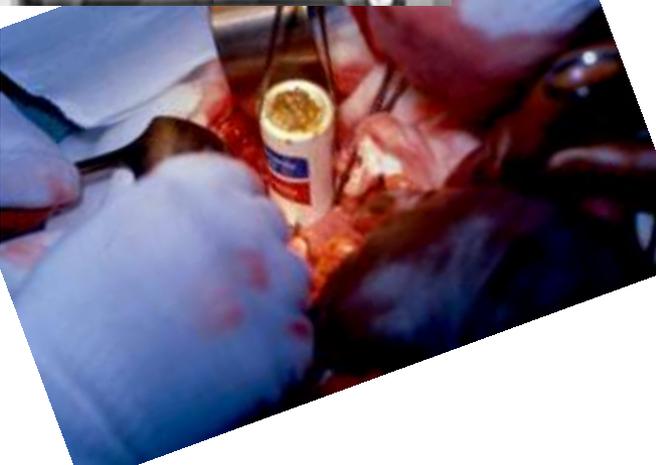




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Dall'arte alle linee guida
attraverso l'evidenza

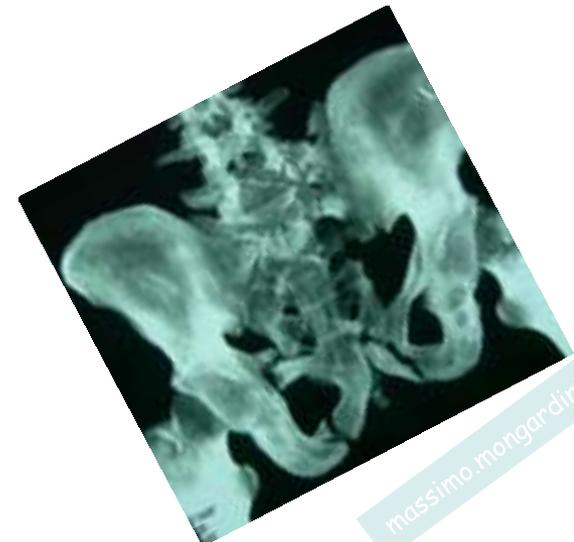
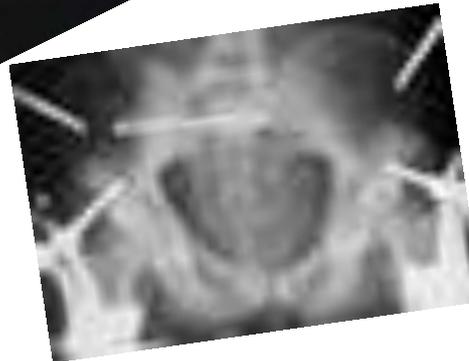
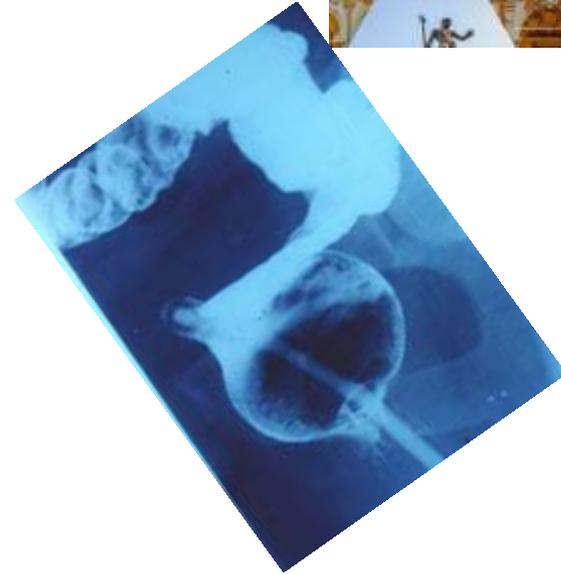
Boezio, 5 - 8 ottobre 2019



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Abbiamo analizzato le lesioni osservate e trattate chirurgicamente presso il nostro istituto negli ultimi 12 anni.

59 pazienti operati $\left\{ \begin{array}{l} 21 \text{ uomini (36\%)} \\ 38 \text{ donne (64\%)} \end{array} \right\}$ età media di 49,8 anni

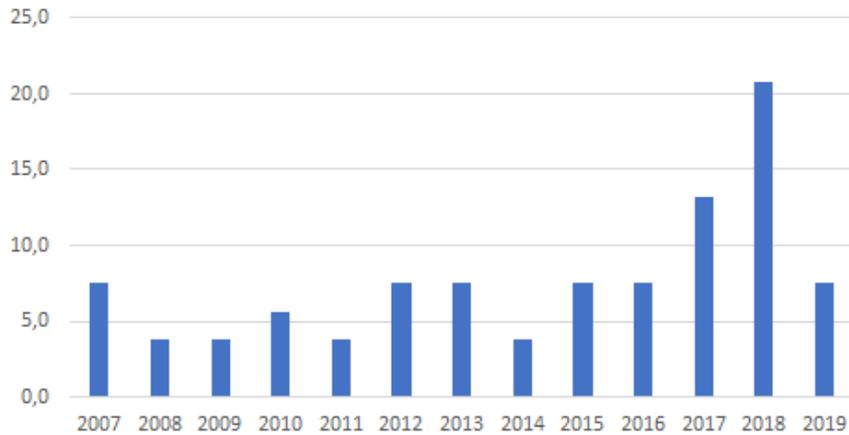
I dati riferiti ai primi tre anni riguardano pazienti trattati nel reparto di chirurgia d'urgenza (DEA) del Policlinico Umberto I, Università di Roma "Sapienza"; i successivi casi sono stati trattati nel reparto di chirurgia generale dello stesso nosocomio



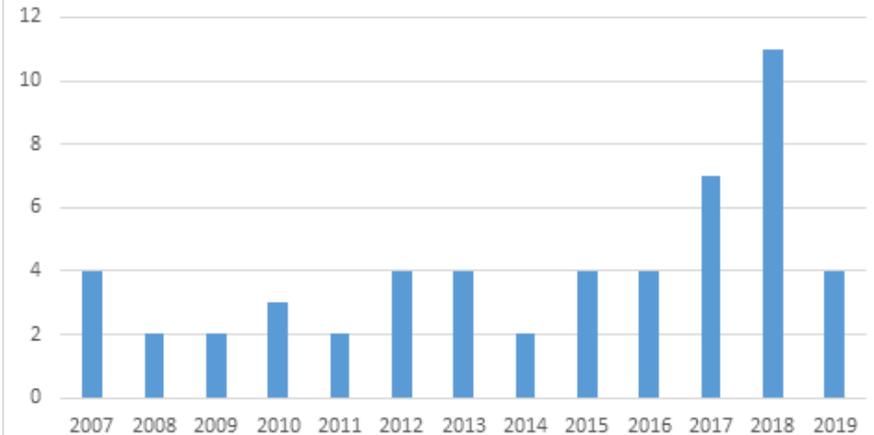
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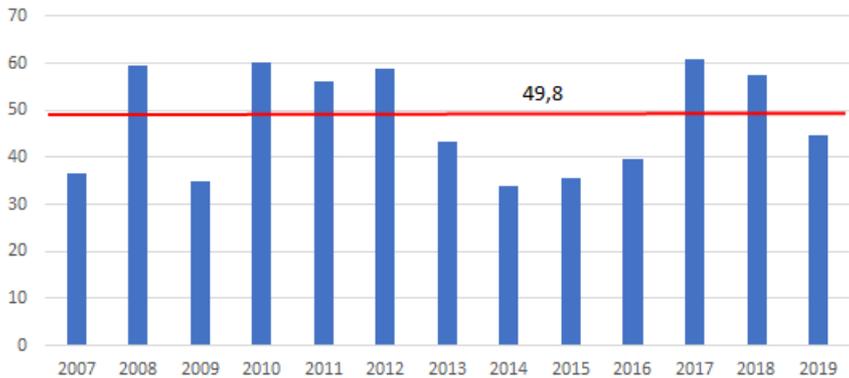
Percentage of patients for each year



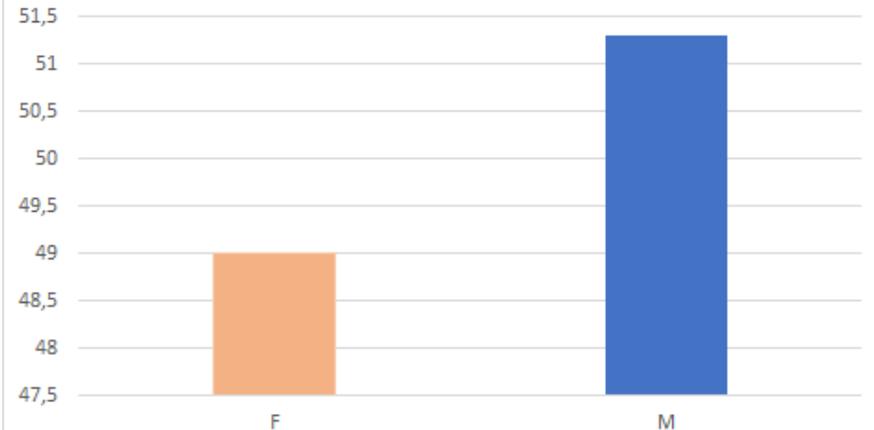
Patients for year



Mean age for each year



Mean age





Prima fase

Analisi statistica delle caratteristiche dei pazienti (sesso, genere per ogni anno e patologie)

Dipendenza tra il tipo di patologia e il genere

- Lesione iatrogena
- Lesione traumatica
- Patologia ascessuale (ASC)
- Patologia neoplastica (NEO);
- Patologia infiammatoria cronica (RCU)

Seconda fase

Analisi delle tipologie di patologia più frequenti in base alle caratteristiche dei pazienti

Terza fase

Tipo di trattamento chirurgico ed incidenza delle diversioni fecali (colostomia: si/no/temporanea/definitiva)

Tutte le variabili sono state analizzate alla luce del Chi Square index, considerando significativo un valore inferiore a 0.05 con livello di confidenza del 95%.



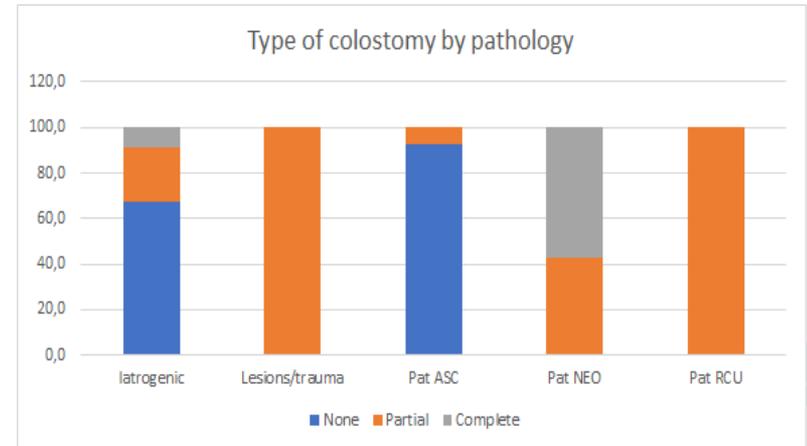
Pathology	Mean age	Female	Male
Other	29,0	0,0	100,0
Iatrogeno	50,9	75,8	24,2
Lesions/trauma	37,8	16,7	83,3
Pat ASC	49,9	50,0	50,0
Pat NEO	64,8	100,0	0,0
Pat RCU	49,0	100,0	0,0

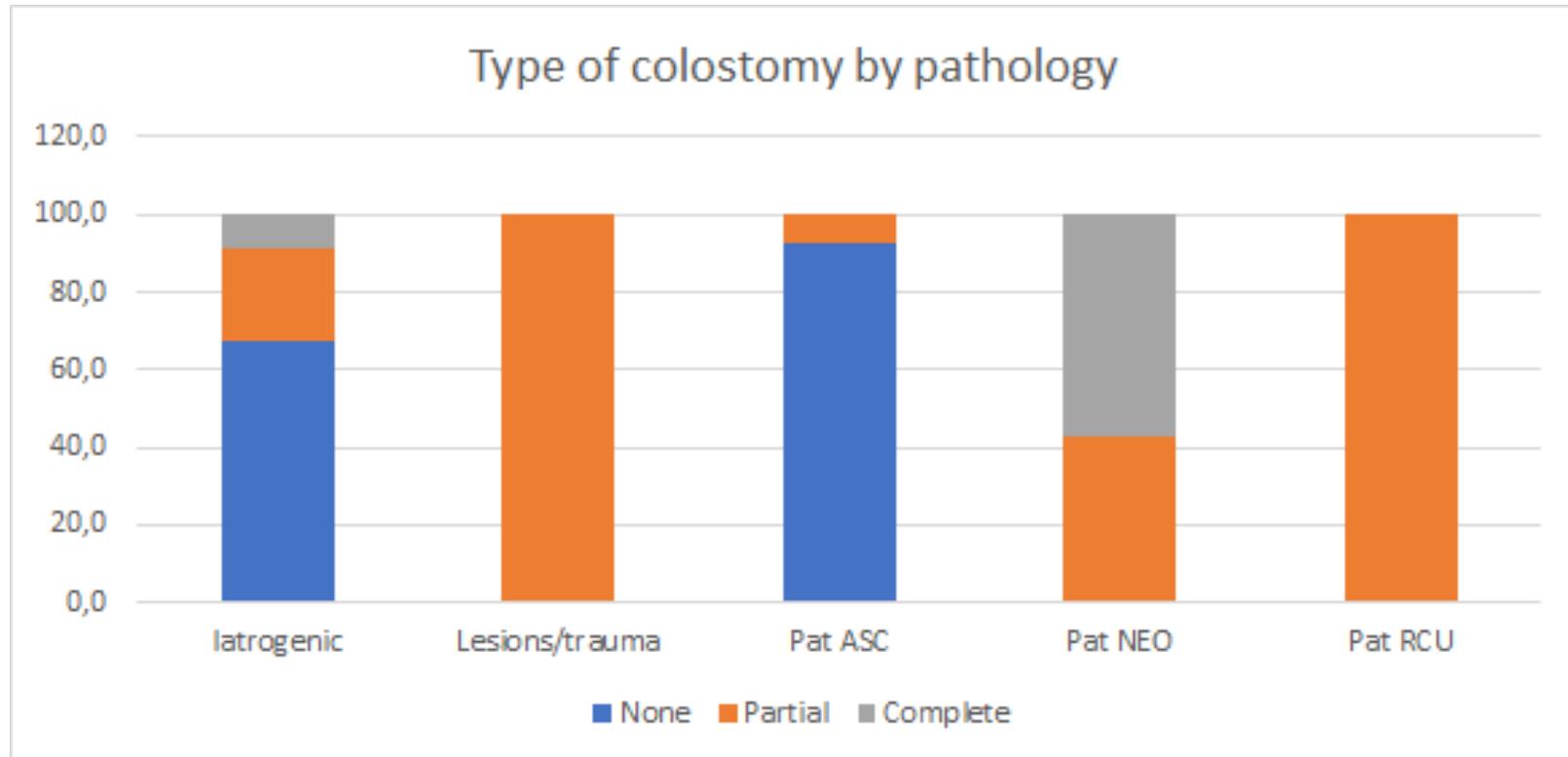
Chi square=13.66, p-value=0.018

Type	Mean age	Female	Male	Total	P-value (gender and pathology)
Fistula	50	92	8	100	0.011
Abscess	43	85	15	100	0.21

Type of colostomy	Iatrogenic	Lesions/trauma	Pat ASC	Pat NEO	Pat RCU	Total
None	23	0	13	0	0	36
Partial	8	6	1	3	1	19
Complete	3	0	0	4	0	7
Totale	34	6	14	7	1	62

Type of colostomy	Iatrogenic	Lesions/trauma	Pat ASC	Pat NEO	Pat RCU	Total
None	67,6	0,0	92,9	0,0	0,0	58,1
Partial	23,5	100,0	7,1	42,9	100,0	30,6
Complete	8,8	0,0	0,0	57,1	0,0	11,3
Total	100	100	100	100	100	100







Le **lesioni** più complesse da trattare sono quelle cosiddette **cloacali**

lesioni che rappresentano una deformità del complesso ano-vagina causato da un danno severo dell'apparato sfinteriale e del corpo perineale

ampia **comunicazione** tra **ano-retto e vagina** responsabile di una invalidante **incontinenza fecale** con gravissimo **scadimento della qualità di vita.**

- Abcarian H, Orsay CP, Pearl RK (1989) Traumatic cloaca. *Dis Colon Rectum* 32: 783-787.
- Kaiser AM (2008) Cloaca-like deformity with fecal incontinence after severe obstetric injury-technique and functional outcome of ano-vaginal and perineal reconstruction with X-flaps and sphincteroplasty. *Colorectal Dis* 10: 827-832
- Mongardini M, Karpathiotakis M (2016) Traumatic Cloaca; Surgical Treatment of a Disabling Deformity. *J Aesthet Reconstr Surg.* 1:1-4.
- Valente MA, Khanduja KS (2012) Layered surgical repair of traumatic cloacal deformities: technical details and functional outcomes. *Tech Coloproctol* 16: 153-156.
- Venkatesh KS, Ramanujam P (1996) Surgical treatment of traumatic cloaca. *Dis Colon Rectum* 39: 811-816.



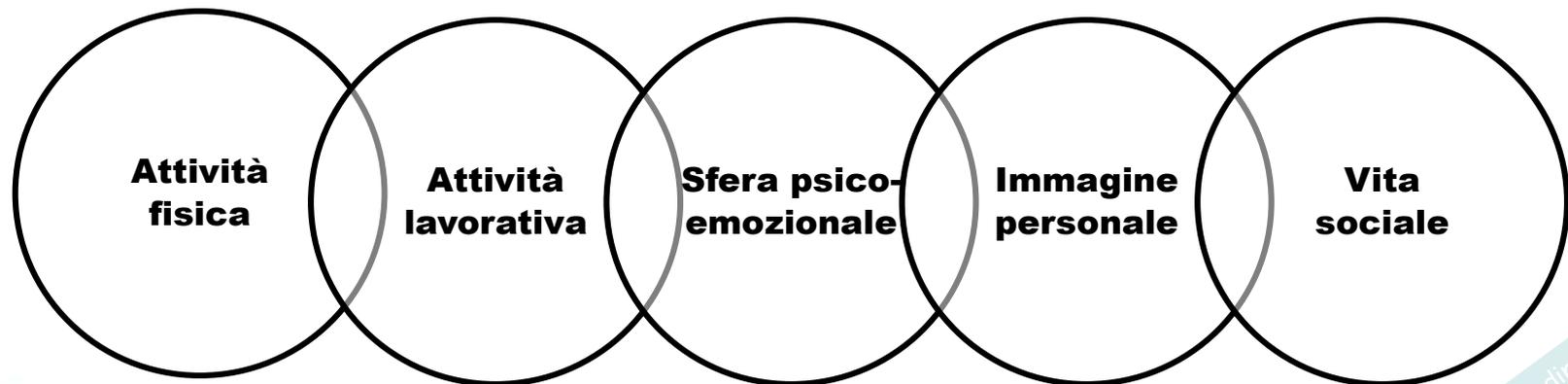
I sintomi prevalenti di un **trauma perineale** ed in particolare di una **lesione cloacale** sono per lo più **funzionali**

1. grave incontinenza a feci e gas
2. dispareunia severa
3. impossibilità ad una normale vita sessuale (*totale o parziale perdita del setto retto-vaginale distale*)
4. severe e ricorrenti irritazioni cutanee perineali (σ e φ) e vaginali (φ)
5. infezioni croniche del tratto uro-genitale

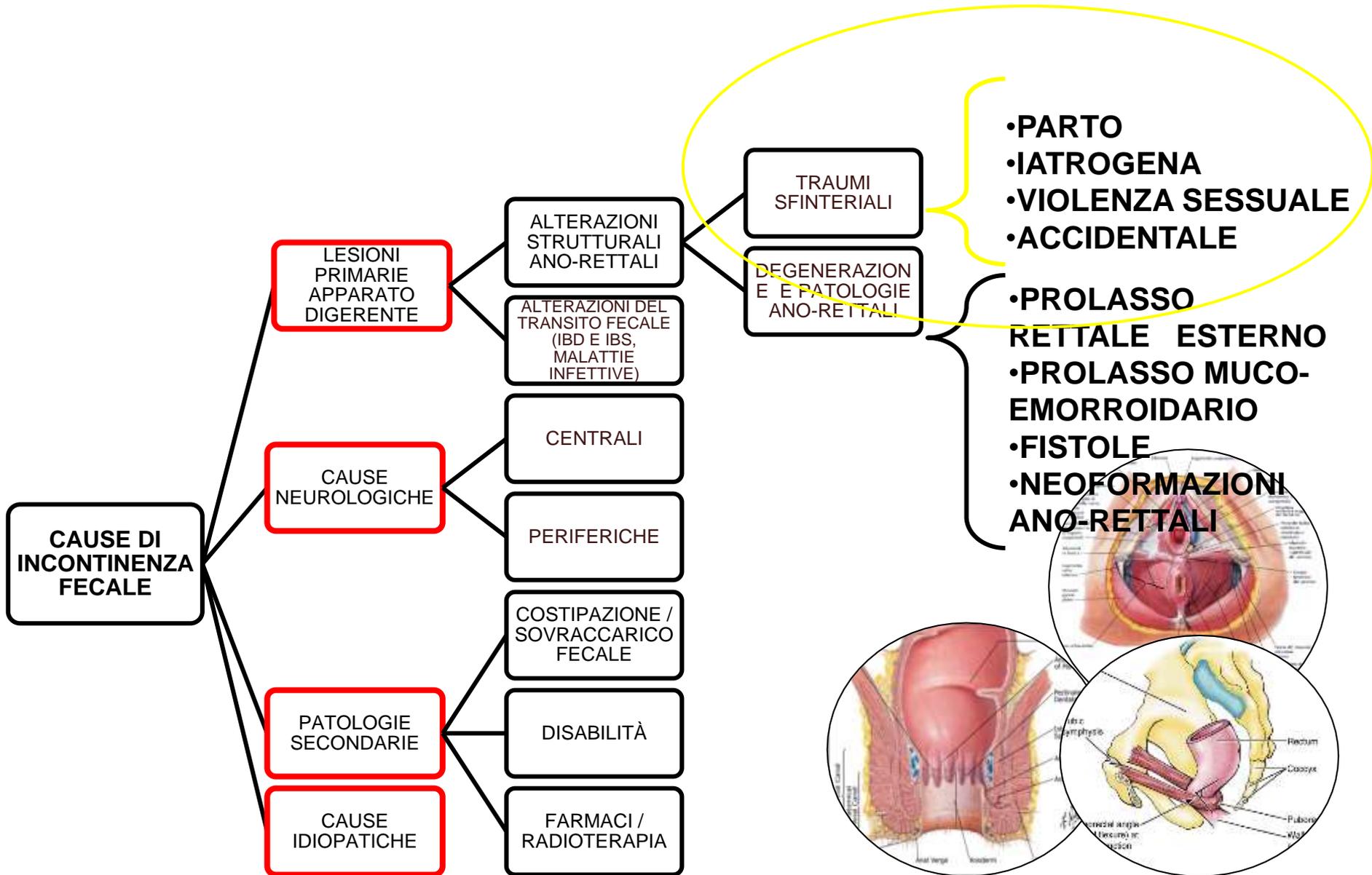


**L'INCONTINENZA FECALE È DEFINITA COME LA
PERDITA DELLA CAPACITÀ DI CONTENERE GAS E FECI
SOLIDE O LIQUIDE.**

PREVALENZA 0,4-18%



ETIOLOGIA



GRAVIDANZA E PARTO

Importante FATTORE DI RISCHIO Vs DISFUNZIONI PERINEALI

Prolasso organi pelvici	32%
Incontinenza urinaria	24%
Dispareunia	23%
Dolore pelvico	10 %
Incontinenza fecale	3-10%

DISFUNZIONI TRANSITORIE DELLA
CONTINENZA (6 mesi)
(urgenza, soiling, incontinenza a gas e/o feci)

DISFUNZIONI PERMANENTI

INCONTINENZA A DISTANZA (mesi, anni)

Fino all'85% parti vaginali – affezioni perineali

PARTO E INCONTINENZA FECALE

DANNO NEUROLOGICO

Compressione n. pudendo durante il parto (compressione canale Alcock)

→ DENREVAZIONE MUSCOLATURA → ALTERATA FUNZIONE

(le lesioni del nervo pudendo persistono o peggiorano dopo 5 anni)

Snooks SJ, Swash M, Mathers SE et al. Effect of vaginal delivery on the pelvic floor: a five-year follow-up. Br J Surg 1990; 2:1358-1360

LESIONI PERINEALI e SFINTERIALI

- PRIMO GRADO → Cute perineale e/o pareti vaginali
- SECONDO GRADO → Muscoli perineali
- TERZO GRADO → Sfintere anale
 - 3a < 50% SAE
 - 3b > 50% SAE
 - 3c SAE + SAI
- QUARTO GRADO → Sfintere anale + mucosa

LESIONI SFINTERIALI

○ LESIONI EVIDENZIATE 1-3%

○ LESIONI OCCULTE

» 35% PRIMIPARE

» 44% PLURIPARE

- Lesioni non evidenziate al parto
- Spesso quadri asintomatici o paucisintomatici (nel breve periodo)
- Possibile iniziale compensazione della muscolatura pelvica
- Evoluzione subdola
- Futura comparsa ulteriori fattori di rischio (età, menopausa, altri parti, chirurgia)

L'incidenza clinica di lacerazioni di terzo e quarto grado variano notevolmente. La prevalenza è dello **0.5-3%** in Europa e del **6-9%** negli USA

DIAGNOSI

L'incontinenza fecale è un sintomo non una diagnosi.

ANAMNESI

ATTIVA

PASSIVA

ESAME OBIETTIVO

ISPEZIONE ED
ESPLORAZIONE RETTALE

MANOMETRIA

IMAGING

ECOSONOGRRAFIA
ENDOANALE

RM-PAVINENTO
PELVICO

(DEFECOGRRAFIA)

DEFECO-RM

INDAGINI ELETTROMIOGRAFICHE

EMG

ELETTROMIELOGRAFIA

PNTML

POTENZIALI
MOTORI EVOCATI

CLASSIFICAZIONE

CCIS

The WEXNER SCORE
A Frequency Assessment Tool

Type of Incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wear Pad	0	1	2	3	4
Lifestyle altered	0	1	2	3	4

FISI

FISI
Fecal Incontinence Severity Index

Q 1: For each of the following, please indicate on average how often in the past month you experienced any amount of accidental bowel leakage:

	1 or More Times a Day	Once a Day	1 or More Times a Week	Once a Week	1 to 3 Times A Month	Never
a. Gas	<input type="checkbox"/>					
b. Mucus	<input type="checkbox"/>					
c. Liquid Stool	<input type="checkbox"/>					
d. Solid Stool	<input type="checkbox"/>					

FECAL INCONTINENCE QUALITY OF LIFE (FIQL)



Tra il 2008 ed il 2018

7 (11,6% delle lesioni totali)
lacerazioni perineali di IV grado

{	6 (10%) trauma ostetrico,
	1 (1,6%) da violenza sessuale.

Età media delle pazienti: 33 anni (25-50)

Colostomia escludente: 3 pazienti (42,85%)



Un **approccio** inizialmente **conservativo** può portare a ritardare il trattamento chirurgico, cronicizzare e aggravare il quadro clinico e **diminuire, di conseguenza, il successo del trattamento ricostruttivo.**

Risultati:

Nell'immediato periodo post-operatorio

Non complicanze di rilievo:

1 infezione della ferita chirurgica con parziale deiscenza, guarita per II intenzione,
1 ematoma risoltosi spontaneamente.



Follow-up a 30 giorni confermava l'eccellente risultato estetico ed una apparente valida attività sfinteriale



Risultati:

A sei mesi la maggioranza delle pazienti (senza colostomia) confermava una discreta continenza sfinteriale (solo due pazienti utilizzavano prudenzialmente un pannolino) ed una iniziale attività sessuale

A sei mesi ricanalizzate le colostomie.

Risultati:

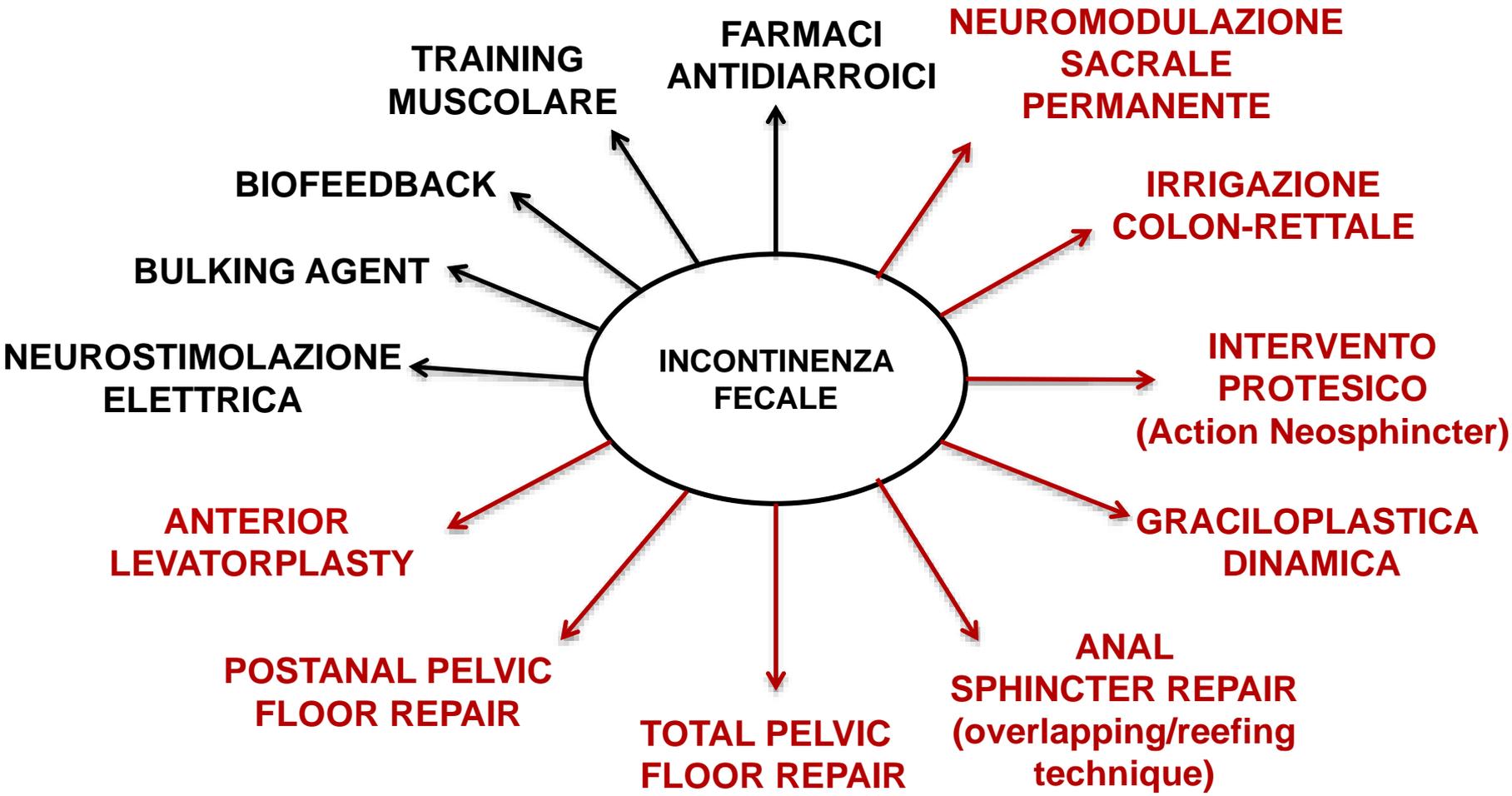
a 12 mesi

- buon risultato estetico
- valida ripresa dell'attività sfinteriale
- soddisfacente controllo delle feci (*nei due casi di pazienti più giovani*) e con immediata riparazione del danno, anche con buon controllo dei gas





TRATTAMENTI



TRATTAMENTI NON CHIRURGICI



TRATTAMENTI CHIRURGICI





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Surgery for faecal incontinence in adults (Review)

Brown SR, Wadhawan H, Nelson RL



This is a review of a Cochrane review proposal and examined by The Cochrane Collaboration and published in The Cochrane Library 2018, Issue 7

<https://www.cochranelibrary.com>



Surgery for faecal incontinence in adults (Review)
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Authors' conclusions

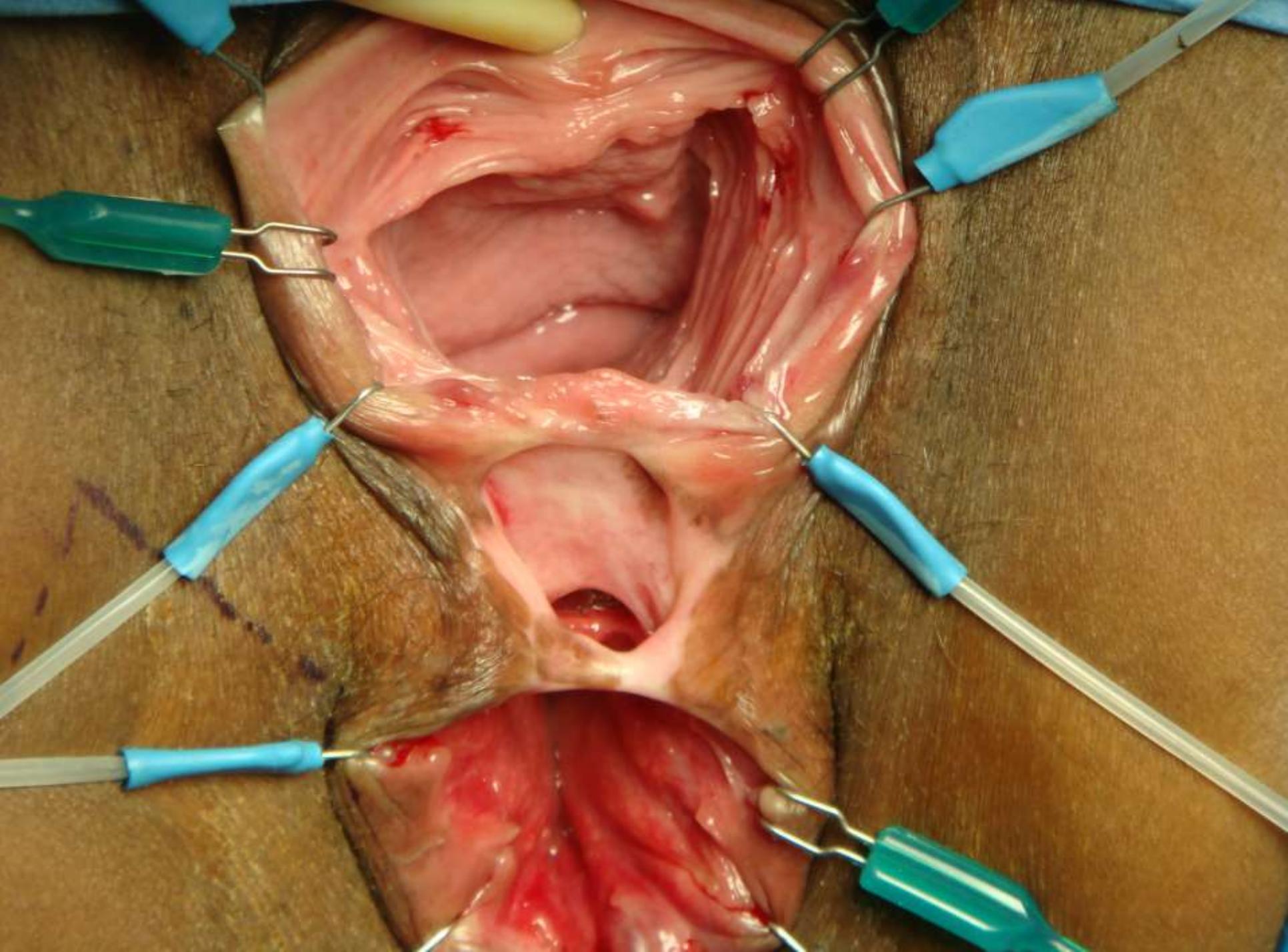
Despite more studies being included in this update, the continued small number of relevant trials identified together with their small sample sizes and other methodological weaknesses continue to limit the usefulness of this review for guiding practice. It was impossible to identify or refute clinically important differences between the alternative surgical procedures. Larger rigorous trials are still needed. However, it should be recognised that the optimal treatment regime may be a complex combination of various surgical and non-surgical therapies.

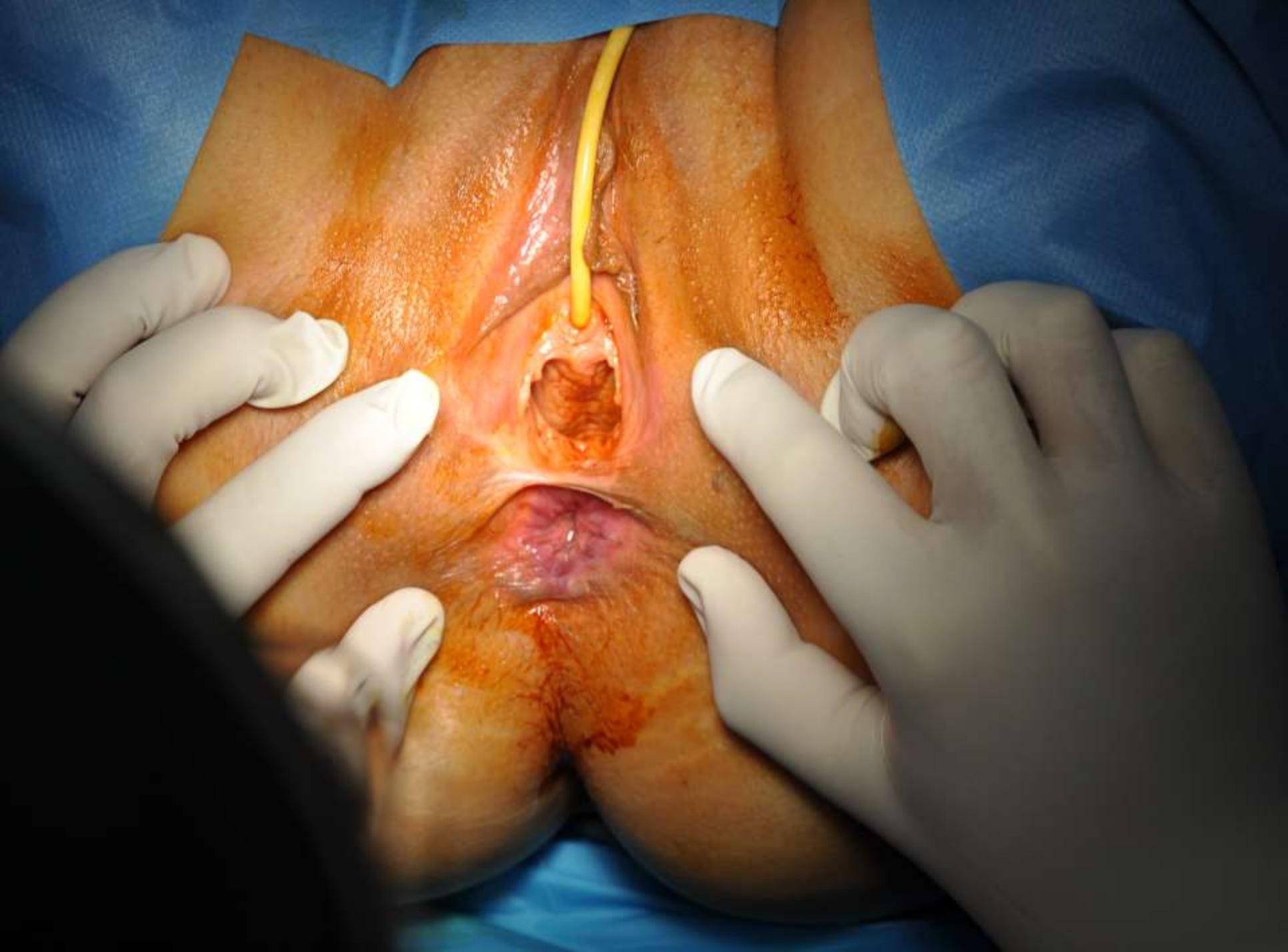


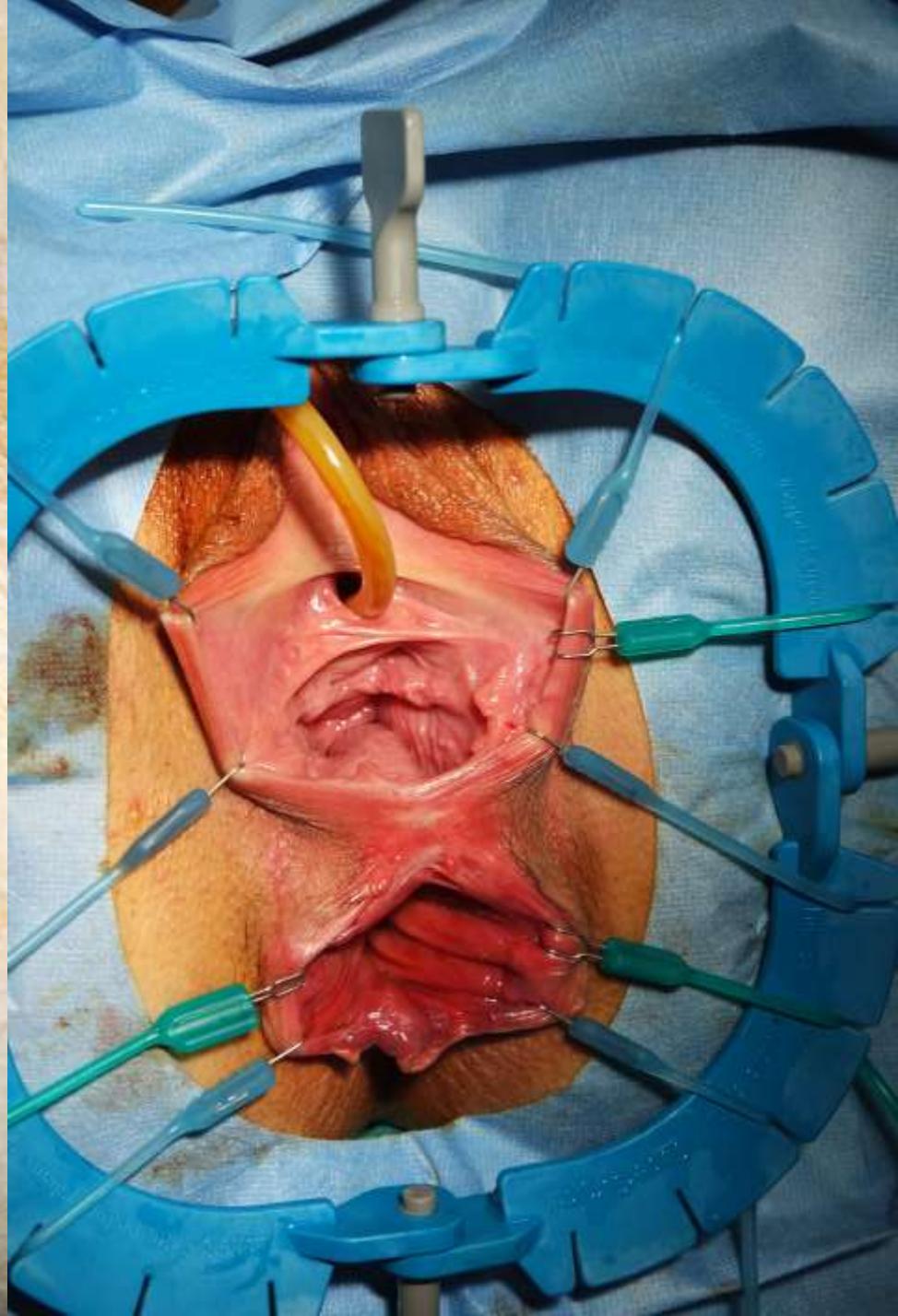
Implications for practice

Although there are now some studies comparing surgical intervention with conservative treatment, the interventions are diverse, the outcomes remain varied and the participant numbers are too small to provide meaningful evidence for practice. With the limited numbers of participants and the single study evidence in mind there may be some very guarded implications for practice:

1. Routinely defunctioning the rectum by creating a stoma after sphincter repair in uncomplicated cases does not improve the outcome of the repair but does increase morbidity and hospital stay.
2. Artificial bowel sphincter may be better than conservative treatment but has significant morbidity.
3. It does not matter whether a sphincter repair is overlapped or directly apposed, the outcome is the same.
4. It may be that some of the outcomes of surgery can be improved by the use of supplementary biofeedback.



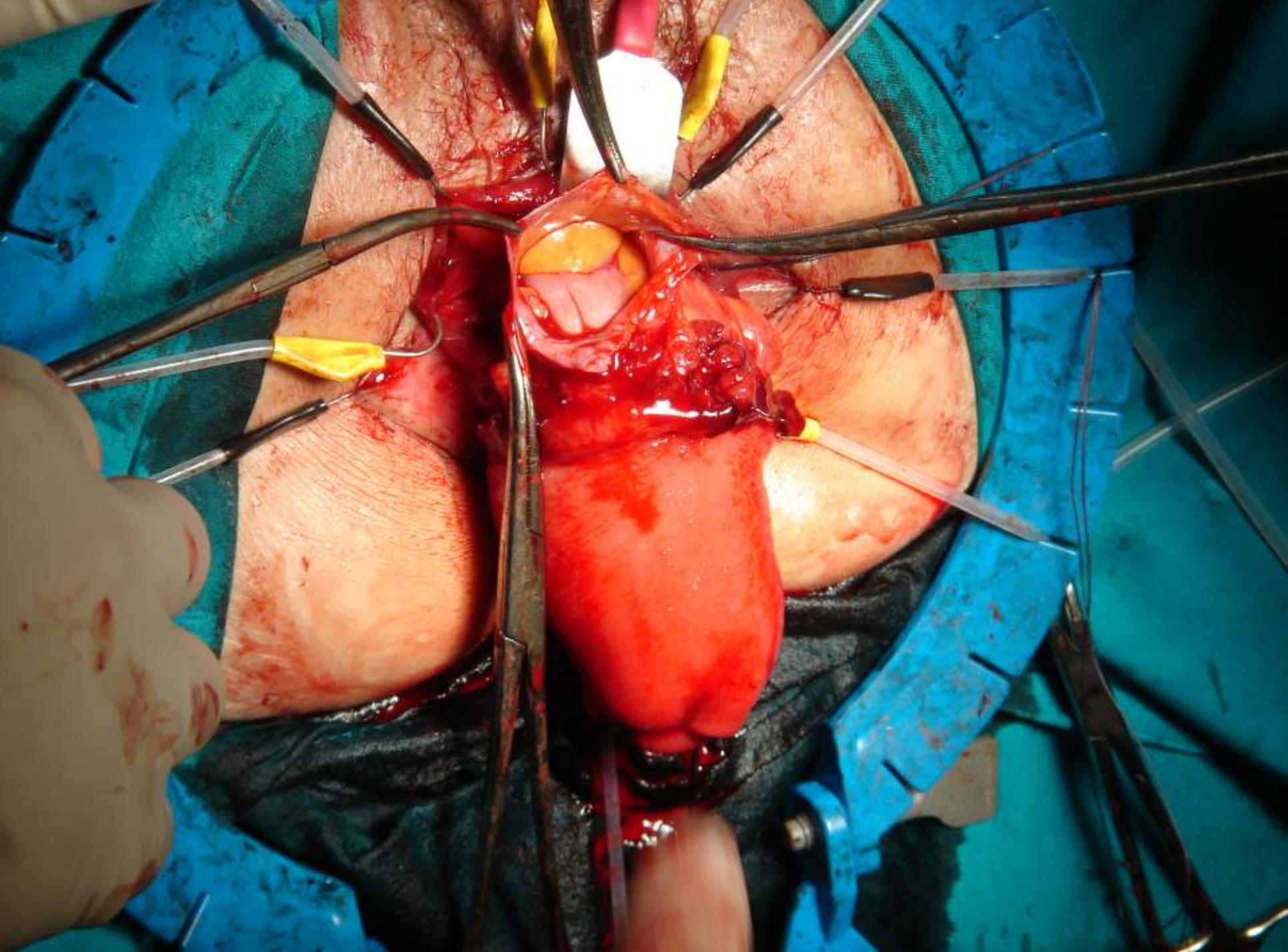


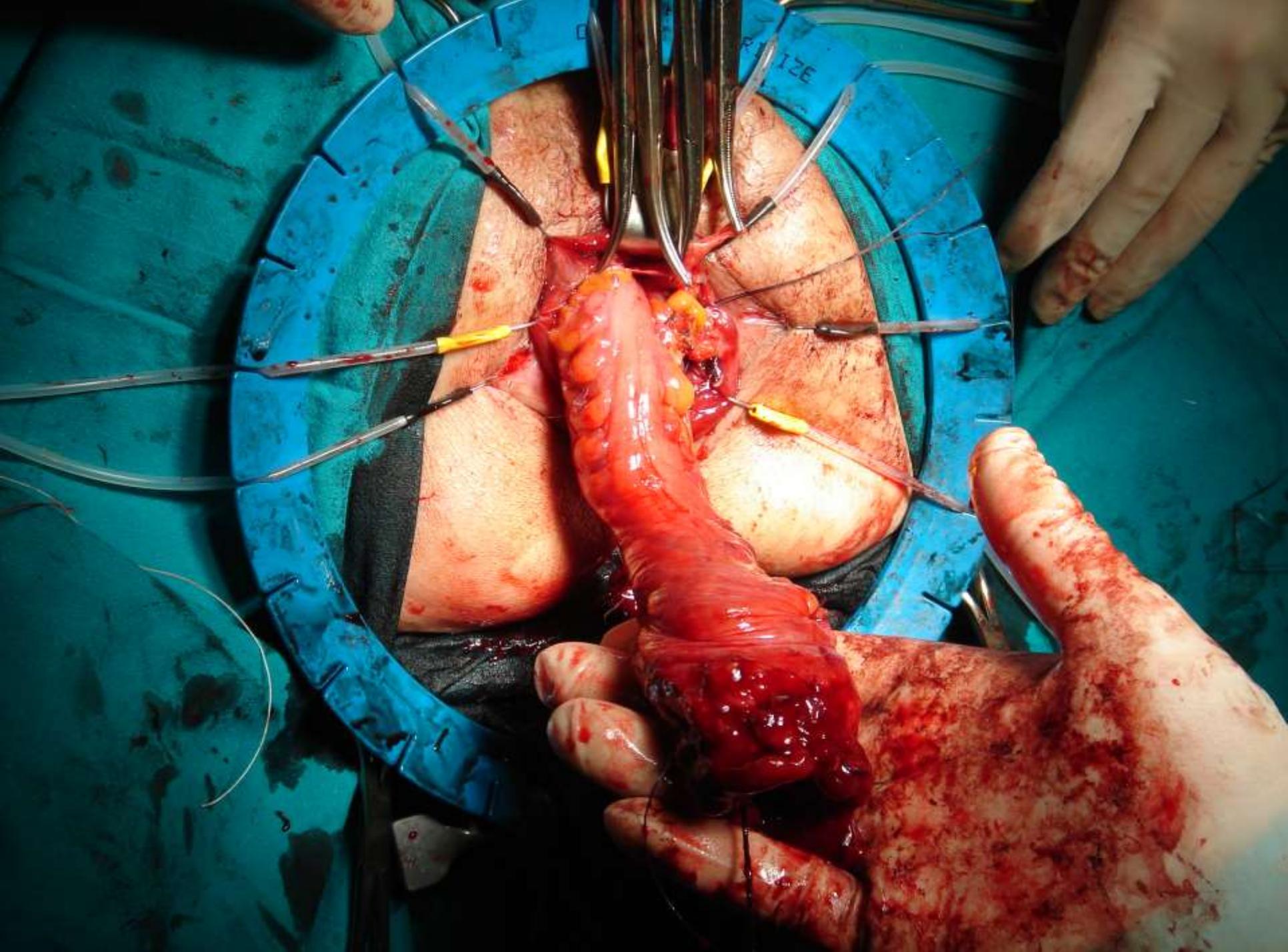




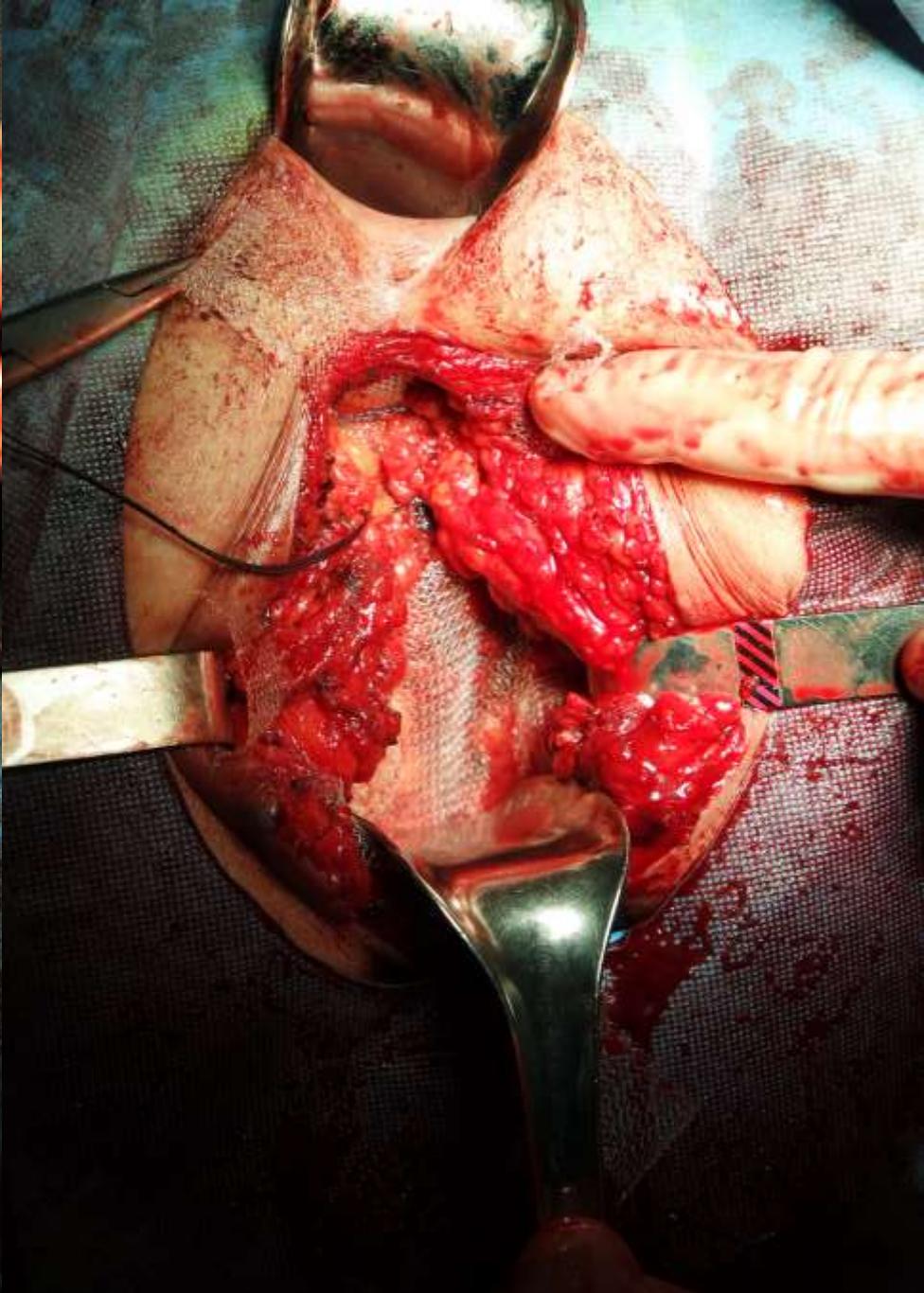
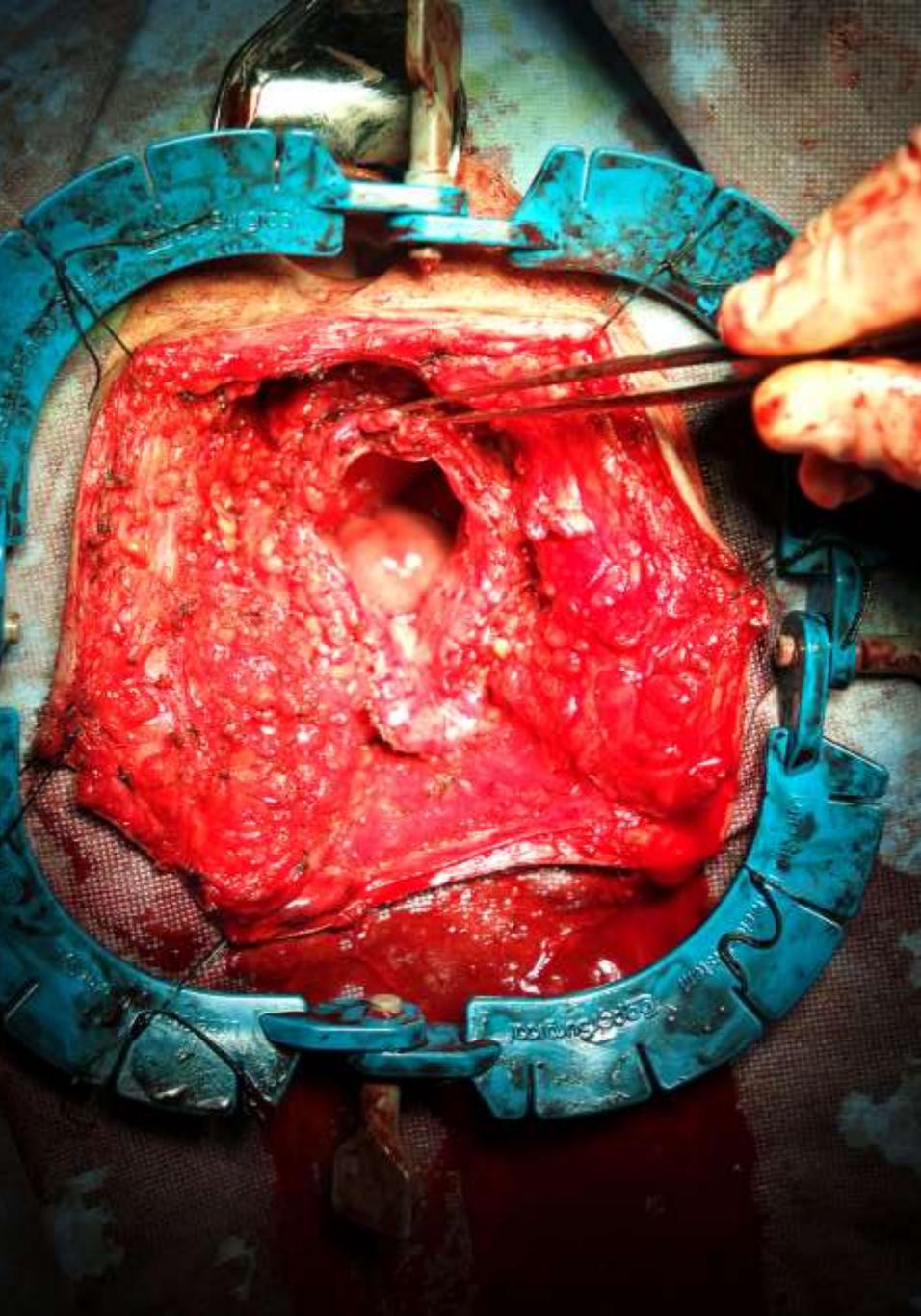
METRIC INCHES
1 2 3 4
Devon
OR Products & Safety Soft





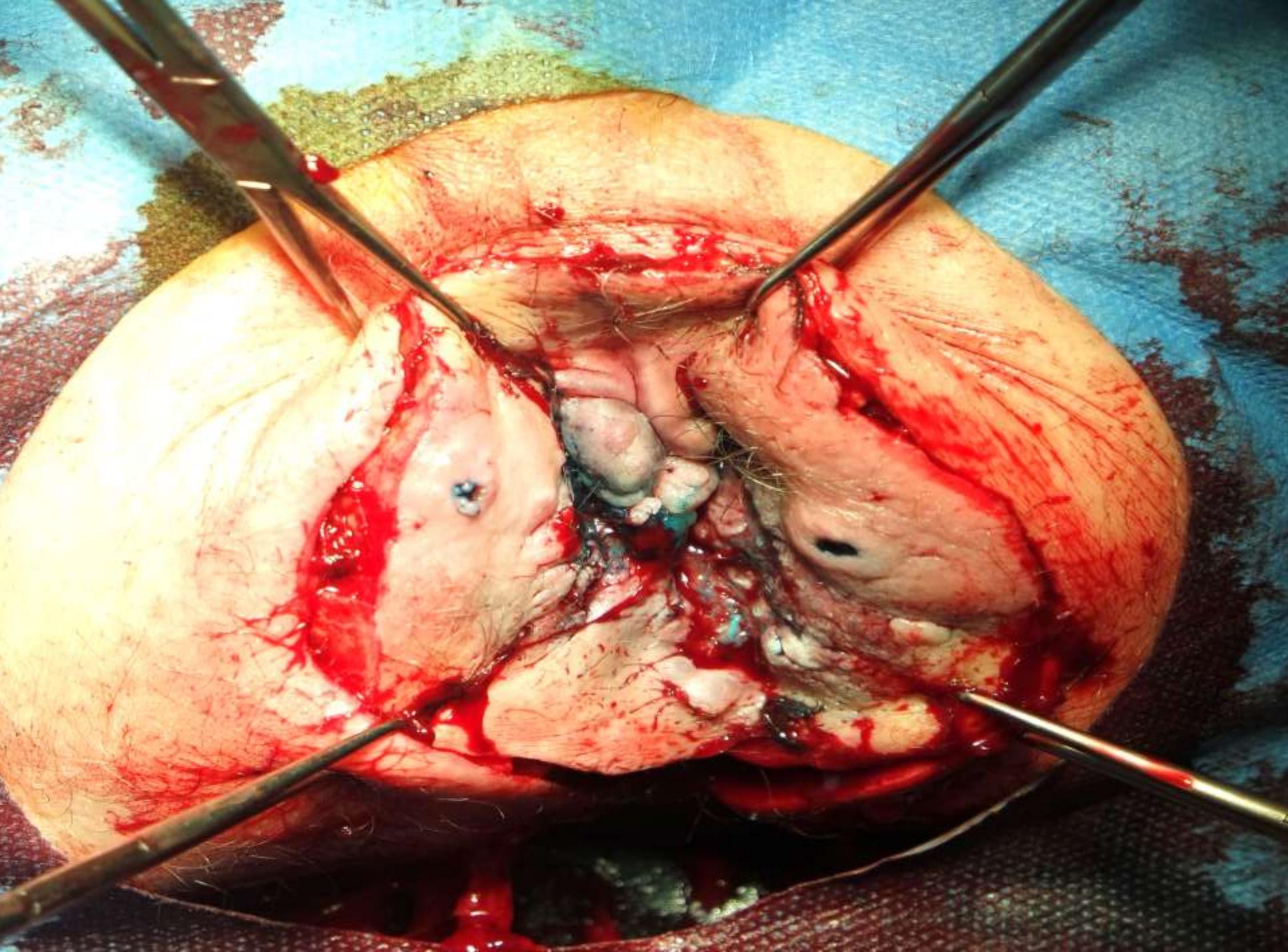


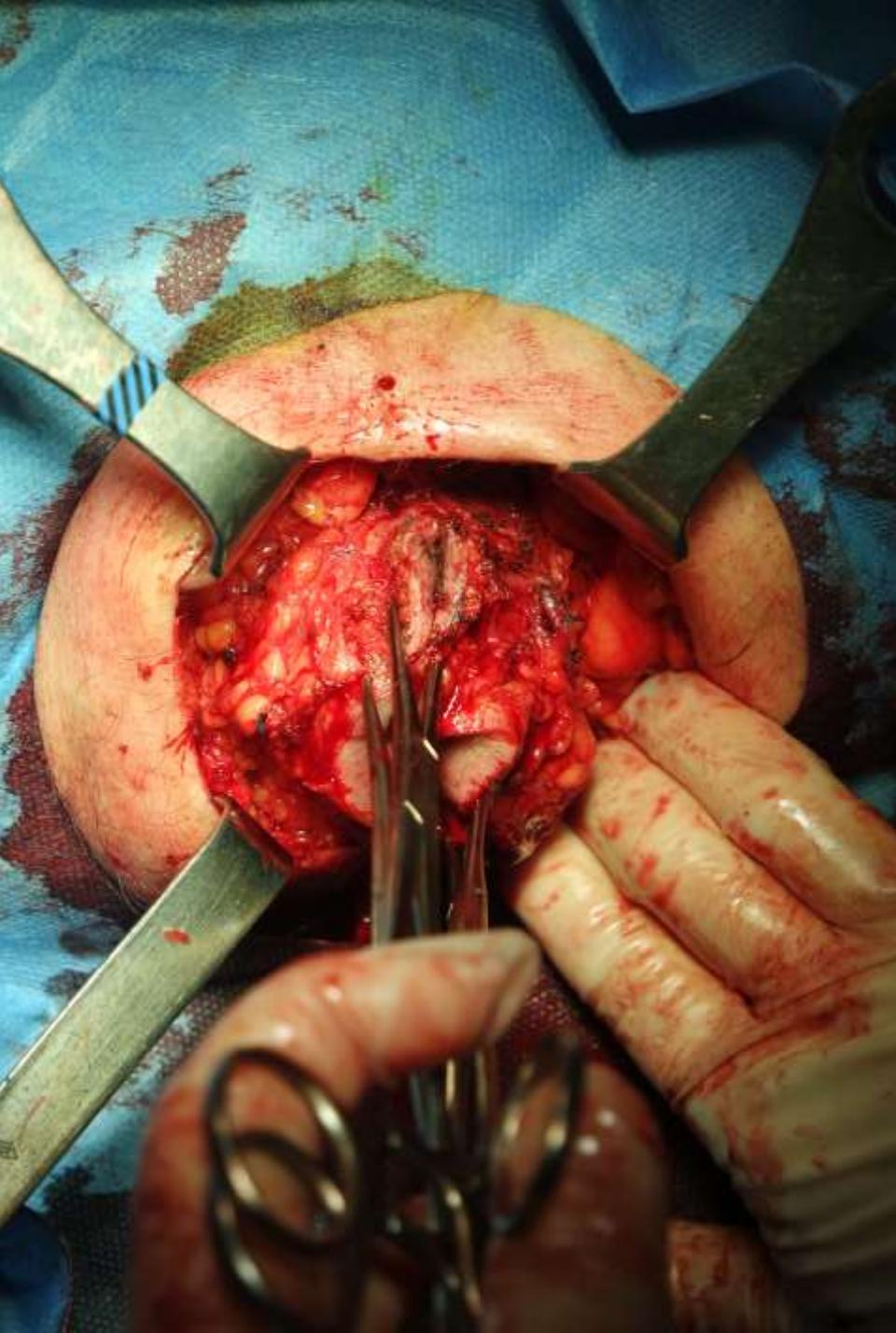












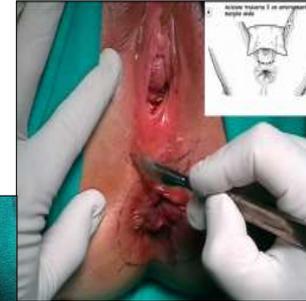


LA NOSTRA ESPERIENZA

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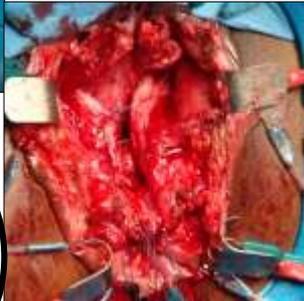
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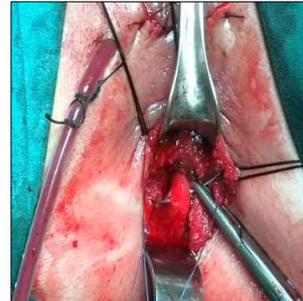
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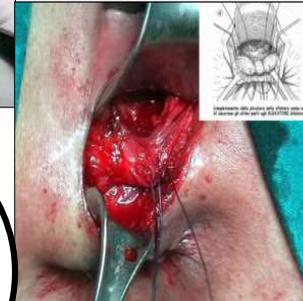
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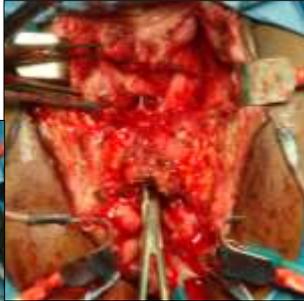
RICOSTRUZIONE RETTO-VAGINALE E SFINTERIALE DA LESIONE CLOACALE

TOTAL PELVIC FLOOR REPAIR DA LESIONE DA PARTO

5



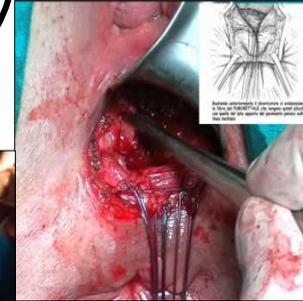
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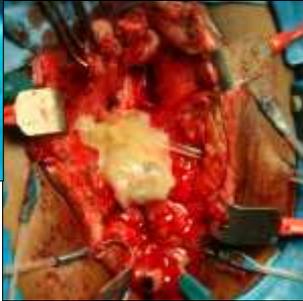
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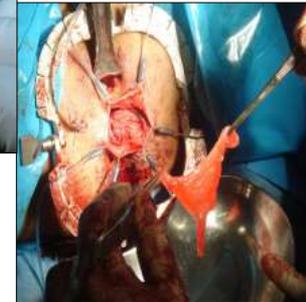
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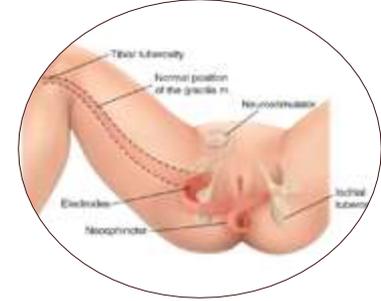
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LA NOSTRA ESPERIENZA



11

1

10

2

9

3

ALTEMEIER +
GRACILOPLASTICA
DINAMICA PER
PROLASSO RETTALE
ESTERNO E
INCONTINENZA
PASSIVA DA LESIONE
IATROGENA



8



7



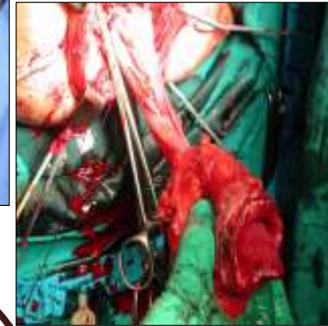
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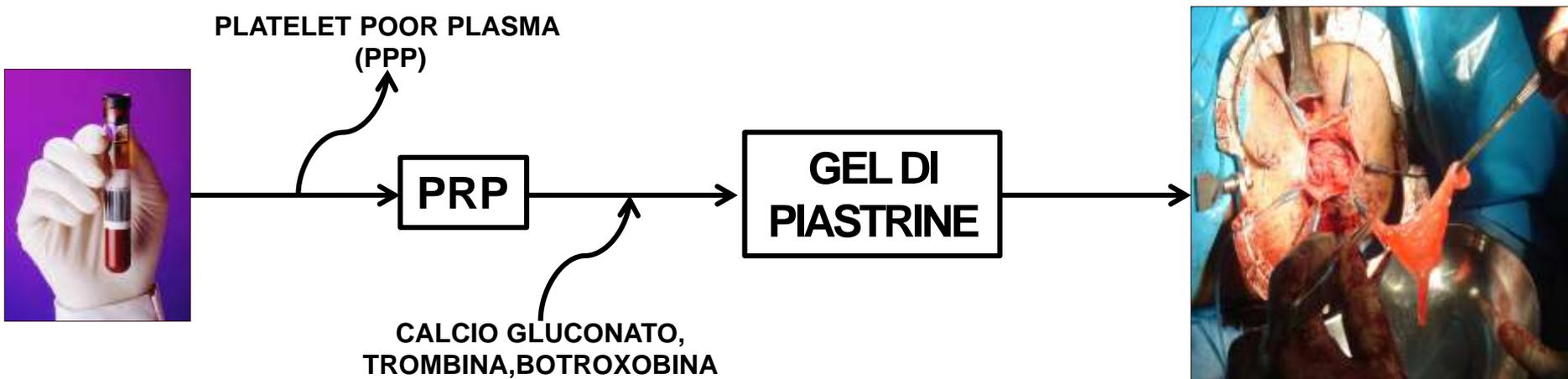


FATTORI DI CRESCITA

- PDGF
 - VEGF
 - FGF-2.
- ↑ NEOANGIOGENESI +
NEOFORMAZIONE TESSUTO MUSCOLARE

PLATELET RICH PLASMA (PRP) E GEL DI PIASTRINE

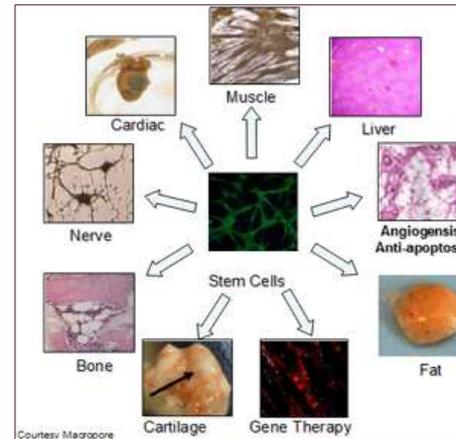
PIASTRINE + FATTORI DI CRESCITA (PDGF, VEGF, IGF-1, EGF)





CELLULE STAMINALI DA:

- **MUSCOLO ADULTO
(CELLULE SATELLITI)**
- **CORDONE OMBELICALE**



IL NOSTRO PROGETTO: cellule staminali ottenute dal muscolo adulto per la ricostruzione del complesso sfinteriale.

- “...il muscolo elevatore dell’ano, inciso e poi trattato con cellule mioblastiche autologhe, si arricchiva di microtubuli esprimenti miosina..” (Ryoko et al. 2009)*
- “...le cellule staminali iniettate sullo sfintere anale esterno hanno rafforzato lo sfintere e aumentato la contrazione sfinteriale..”(Sung-Bum Kang et al.2008)*
- “...le cellule mioblastiche iniettate sul muscolo sfintere esterno in donne con lacerazione da parto di III e IV grado, hanno aumentato la contrazione muscolare e migliorato i sintomi..”(Frudinger et al. 2010)*

Massimo Mongardini
Manuel Giofrè
Editors

Management of Fecal Incontinence

Current Treatment Approaches
and Future Perspectives

Mongardini · Giofrè *Eds.*



Management of Fecal Incontinence

Mongardini
Giofrè
Editors
**Management of
Fecal Incontinence**
Current Treatment
Approaches and Future
Perspectives

This book presents state of the art knowledge regarding the pathophysiology and diagnosis of fecal incontinence and describes and illustrates all relevant treatment techniques. In addition to the approaches that have been the mainstay of treatment of fecal incontinence to date, it covers recent innovations and emerging options, including neurostimulation, pioneering techniques exploiting the potential of stem cells, bio-feedback training, reconstructive surgery, and advances in biomedical engineering applicable to replacement surgery. Fecal incontinence is a common, socially debilitating disorder of multifactorial etiology that poses many management challenges. This book will assist all relevant medical specialists, including surgeons, neurologists, gastroenterologists, urogynecologists, and other clinicians, in achieving correct and timely diagnosis and delivering effective therapy that reflects the ongoing revolution in treatment.

Surgery

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CONCLUSIONI (1)

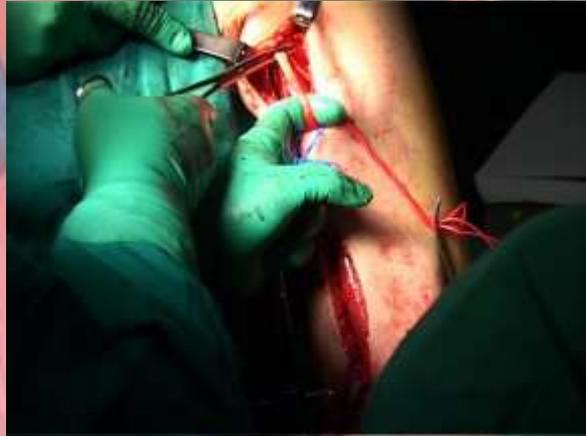
- Il ***biofeedback*** non è indicato nelle lesioni sfinteriali di grado severo perché, aumentandone la contrazione, dilata ulteriormente il segmento funzionalmente inattivo peggiorando il sintomo.
- I ***bulking agents*** danno una risoluzione temporanea del sintomo poiché prontamente riassorbiti.
- L'intervento di sostituzione protesica è gravato da complicanze infettive e ulcerazioni tissutali.
- Nei casi di incontinenza secondaria a prollasso rettale esterno, la riduzione della ridondanza mucosale migliora l'incontinenza.



CONCLUSIONI (2)

- **Anticipando l'intervento chirurgico migliorano i risultati.**
- **La giovane età dei pazienti garantisce una migliore ripresa funzionale.**
- **Il *Platelet Rich Plasma* (PRP) ed il Gel di Pastrine applicati come complemento all'intervento chirurgico sulle lesioni tissutali, consolidano i tessuti velocizzandone la ripresa funzionale.**
- **I presupposti teorici e i primi risultati sull'utilizzo delle cellule staminali in campo proctologico, fanno ben sperare nel loro utilizzo per il trattamento ricostruttivo delle lesioni sfinteriali.**

Graciloplastica dinamica (1)



K.L. Pickrell *Annals of Surgery*, June 1952

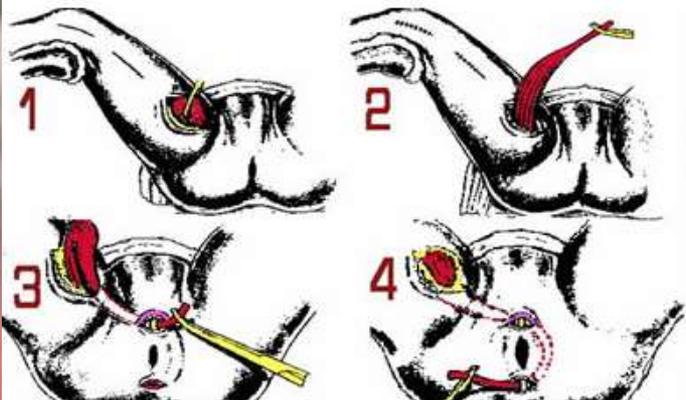


CONSTRUCTION OF A RECTAL SPHINCTER AND RESTORATION OF ANAL CONTINENCE BY TRANSPLANTING THE GRACILIS MUSCLE
A REPORT OF FOUR CASES IN CHILDREN*

KENNETH L. PICKRELL, M.D., T. RAY BRADSHAW, M.D.,
FRANK W. HAYES, M.D., AND JAMES T. METZGER, M.D.
DURHAM, N. C.

FROM THE DIVISION OF PLASTIC SURGERY, DUREN UNIVERSITY SCHOOL OF MEDICINE AND DUREN MEDICAL CENTER.

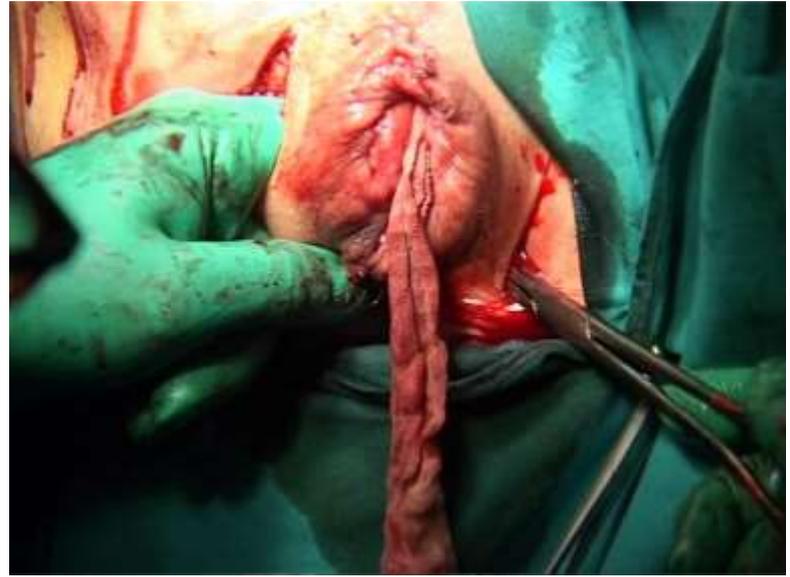
It is the purpose of this presentation to introduce a new principle in anal reconstructive surgery; the transplantation of the gracilis muscle to construct an anal sphincter. No one knows the indelible mental effects produced on those so afflicted. However, at least in seven instances - children to men -



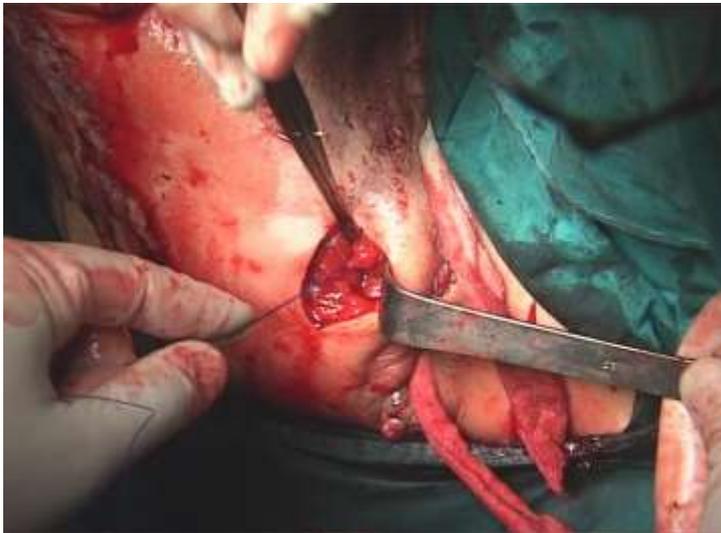
1. Dissection of the gracilis muscle from the back.
2. Mobilization of the muscle flap.
3. Transposition of the muscle flap to the anal area.
4. Anastomosis and fixation of the muscle flap to form a functional sphincter.



Graciloplastica dinamica (2)



Graciloplastica dinamica (3)



Stimulated graciloplasty for faecal incontinence

1 Guidance

- 1.1 Current evidence on the safety and efficacy of stimulated graciloplasty for faecal incontinence is limited, but appears sufficient to support the use of this procedure for carefully selected patients in whom other treatments have failed or are contraindicated, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 This procedure should be performed only in specialist units by clinicians with specific training and experience in the assessment and treatment of faecal incontinence.

2 The procedure

2.1 Indications

- 2.1.1 Stimulated graciloplasty is used to treat refractory faecal incontinence (for example, anorectal atresia) as an alternative to colostomy. Other approaches aimed at establishing continence are insertion of an artificial anal sphincter and sacral nerve stimulation.

2.2 Outline of the procedure

- 2.2.1 Stimulated graciloplasty involves creating a new anal sphincter using transposed gracilis muscle. Electrodes are implanted in the transposed muscle and connected to an electric pulse generator implanted in the abdominal wall. A continuous current from the pulse generator gradually alters the character of the gracilis muscle fibres.
- 2.2.2 The procedure can be performed in one or two stages. In the latter case, the muscle wrapping precedes the electrode implantation stage by a few weeks.

2.3 Efficacy

- 2.3.1 A systematic review of 37 studies of graciloplasty found that between 42% and 85% of patients became continent after the procedure (different definitions of continence were used and continence was assessed at different time points in the studies). A controlled study found that at 24 months, frequency of incontinence had significantly improved from baseline in 48 patients who had undergone graciloplasty ($p < 0.0001$); there was no improvement during this period in patients who were not offered surgery. A case series reported successful outcomes in 72% (144/200) of patients, with 5-year follow-up.
- 2.3.2 A controlled trial found that quality of life improved more in patients treated with graciloplasty ($n = 46$) than in those not offered surgery who were being medically managed ($n = 40$). The following scales were used to assess quality of life: the Cleveland Clinic Faecal Incontinence Scale ($p = 0.001$); the Hospital Anxiety and Depression Scale for anxiety ($p = 0.03$) and depression ($p = 0.05$); and a validated study-specific scale for psychological wellbeing ($p < 0.0001$) and lifestyle characteristics ($p < 0.0001$). In a case series of 129 patients who had graciloplasty, patients' quality of life was significantly improved on the SF-36 scale for physical and social functioning at 12 months' follow-up. For more details, refer to the Sources of evidence.
- 2.3.3 The Specialist Advisors suggested that this procedure has been largely superseded by sacral nerve stimulation.

2.4 Safety

- 2.4.1 The most common complication of stimulated graciloplasty is wound infection. In a systematic review that included 403 patients assessed for safety outcomes, the overall rate of infection was 28%. In a case series of 121 patients, serious infection needing hospitalisation and/or surgery was reported in 15% of patients, and in another series it occurred in 14% (17/123) of patients.
- 2.4.2 Electrical or technical problems with the pulse generator leading to hospitalisation occurred in 48% (23/48) of patients who had undergone graciloplasty in a controlled trial at 42 months' follow-up. In a case series of 123 patients, 3 patients (2%) had a deep vein thrombosis and one patient died following a pulmonary embolism 3 weeks after surgery.
- 2.4.3 In a comparative study 69% (33/48) of patients had evacuation difficulties or pain requiring hospitalisation following graciloplasty. Disturbed evacuation was reported in 16% (32/200) of patients in a prospective case series. For more details, refer to the Sources of evidence.
- 2.4.4 The Specialist Advisors noted that the main reported adverse events were related to the pulse generator, particularly the risk of infection (both in the short and the long term).

3 Further information

- 3.1 The Institute has produced guidance on sacral nerve stimulation for faecal incontinence (www.nice.org.uk/PG099).

Andrew Dillon
Chief Executive
March 2006

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/PG159publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document: 'Interventional procedure overview of stimulated graciloplasty', June 2005.

Available from: www.nice.org.uk/ip019overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0994. Information for the public can be obtained by quoting reference number N0995.

The distribution list for this guidance is available at www.nice.org.uk/PG159distributionlist

Interventional Procedure Guidance 159

This guidance is written in the following context

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

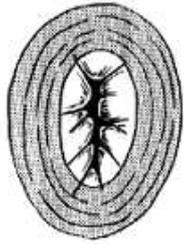
This guidance is endorsed by NHS QIS for Implementation by NHSScotland.



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Overlapping repair (1)



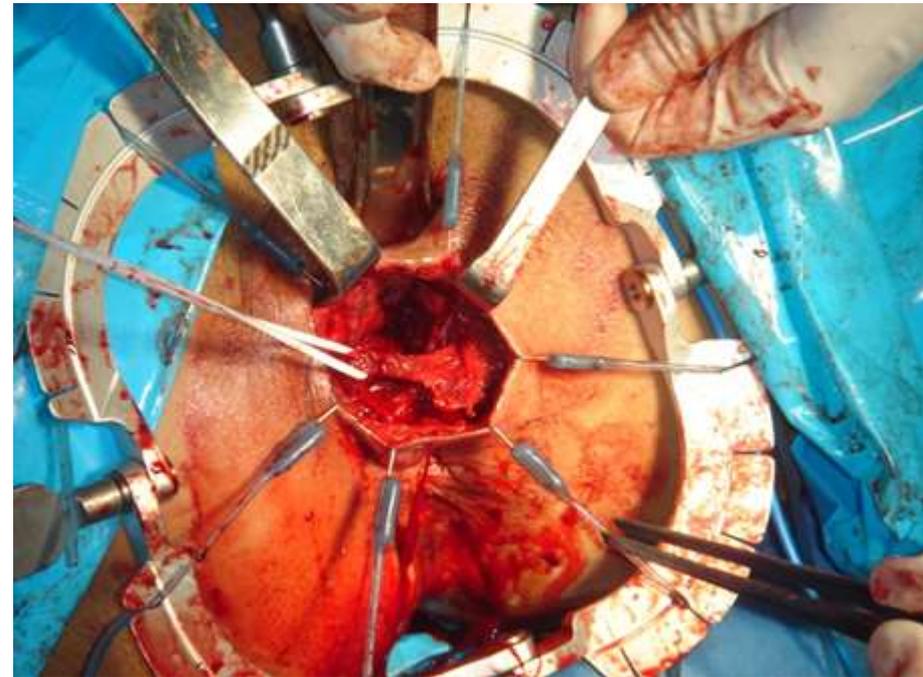
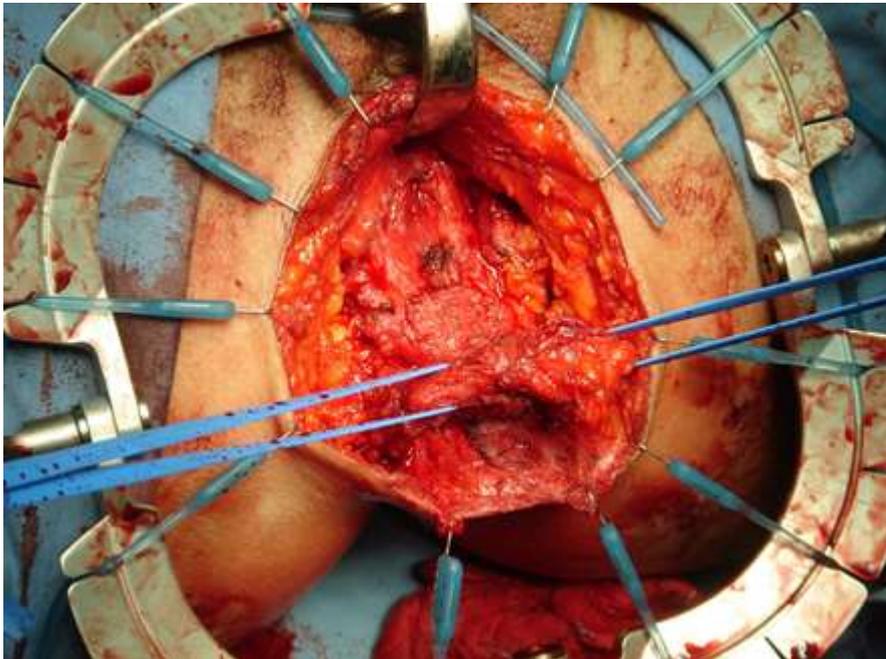
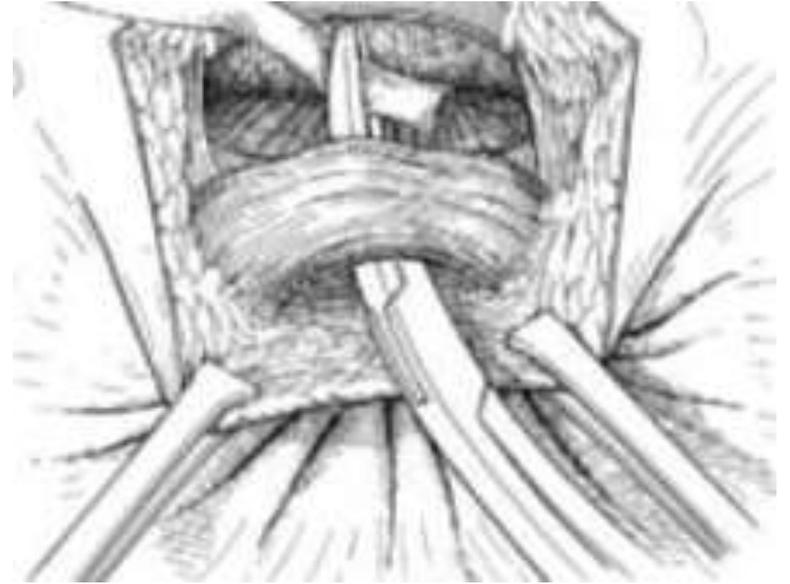
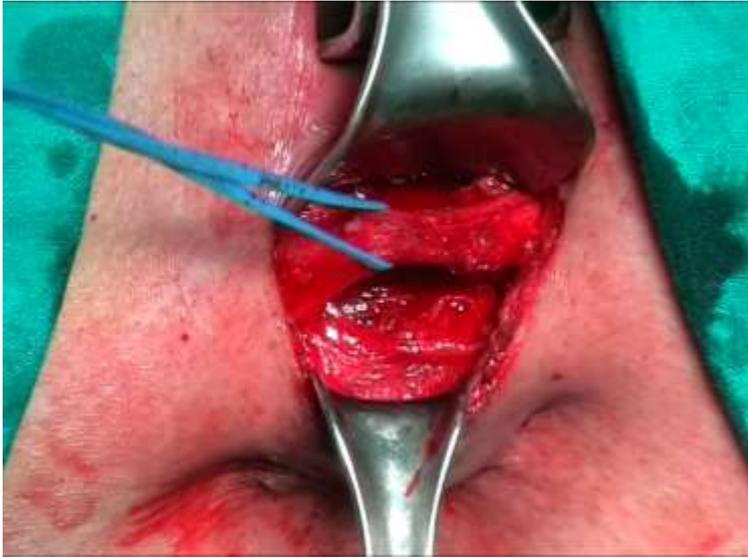
Normal anal sphincter muscle



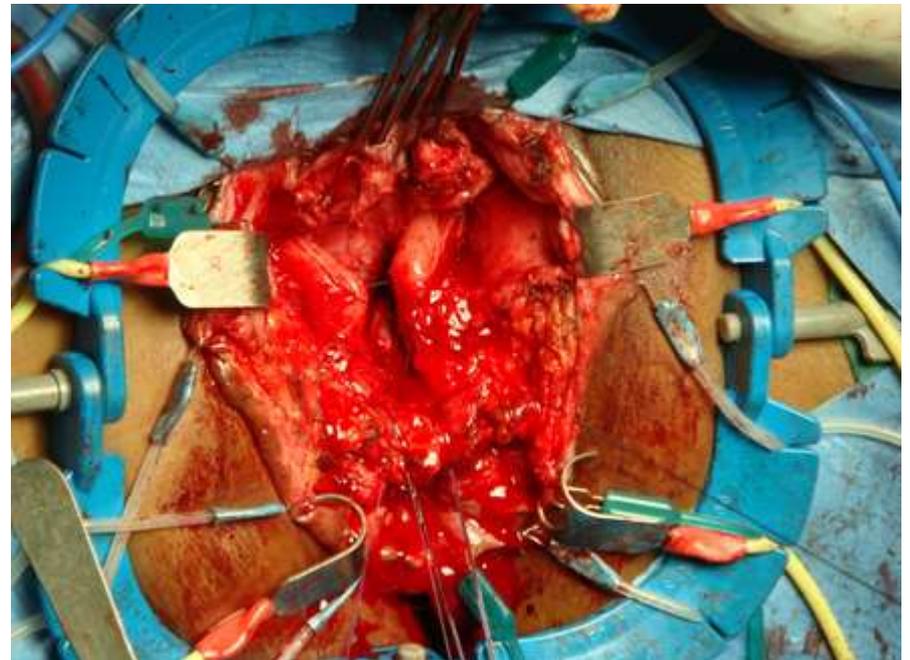
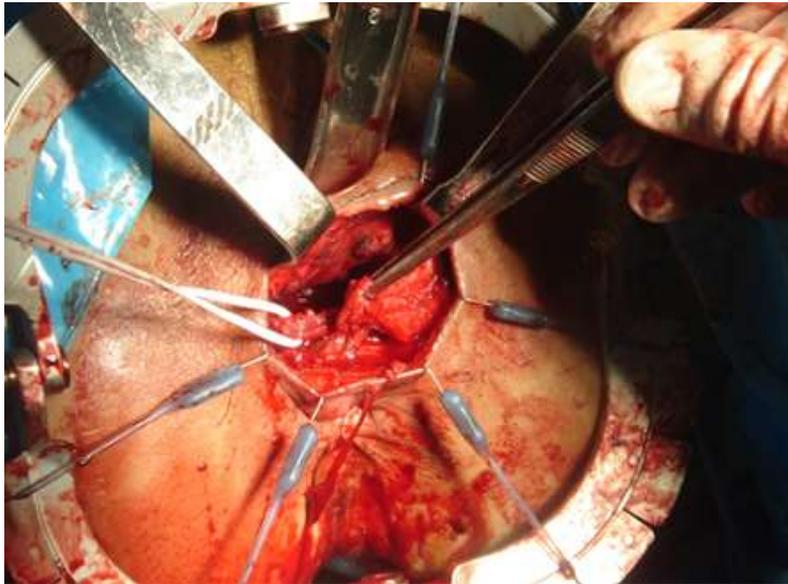
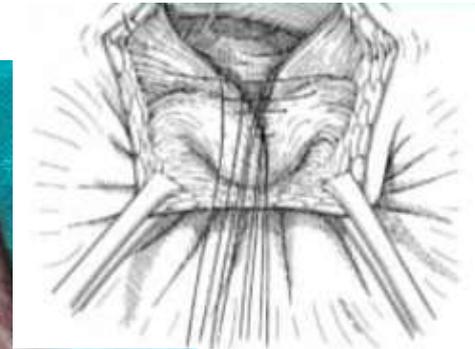
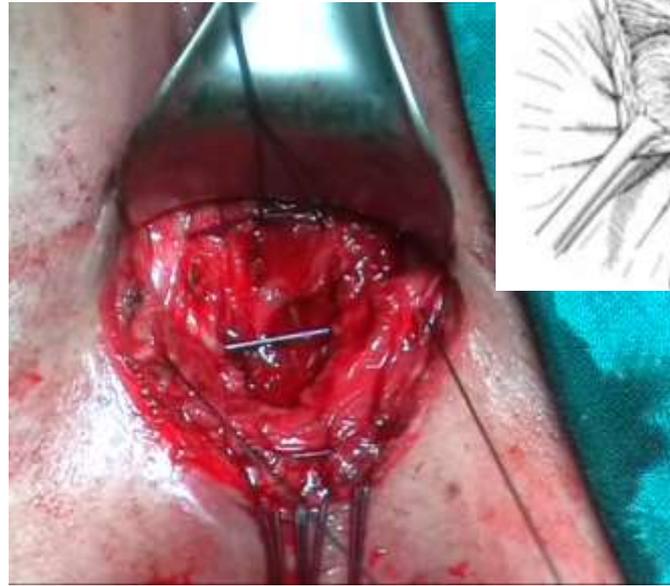
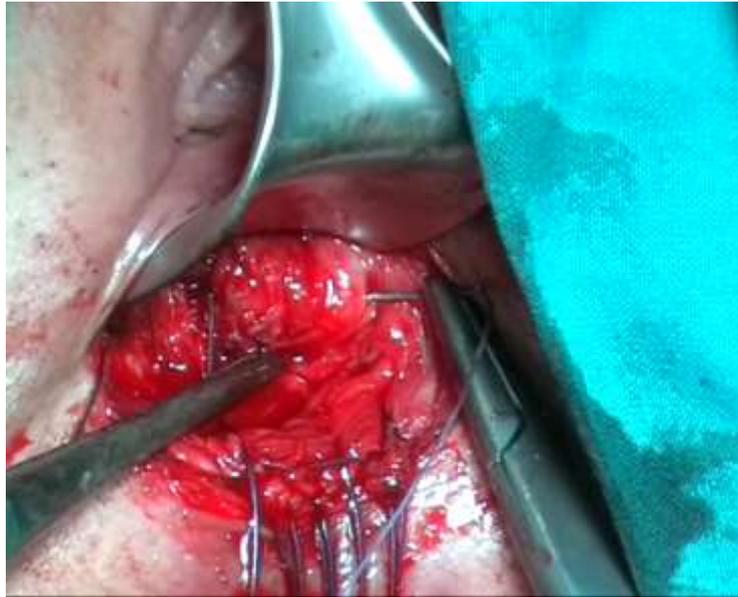
Severed anal sphincter muscle



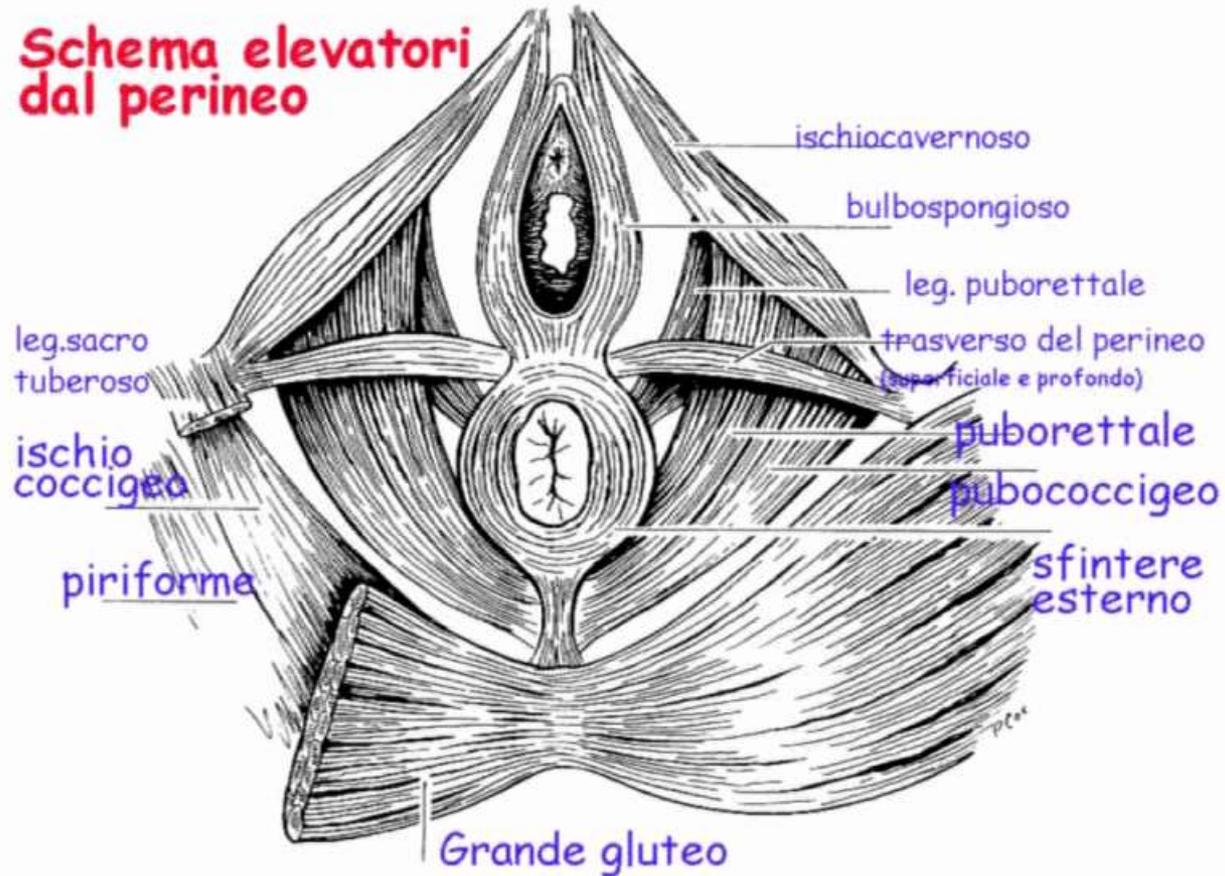
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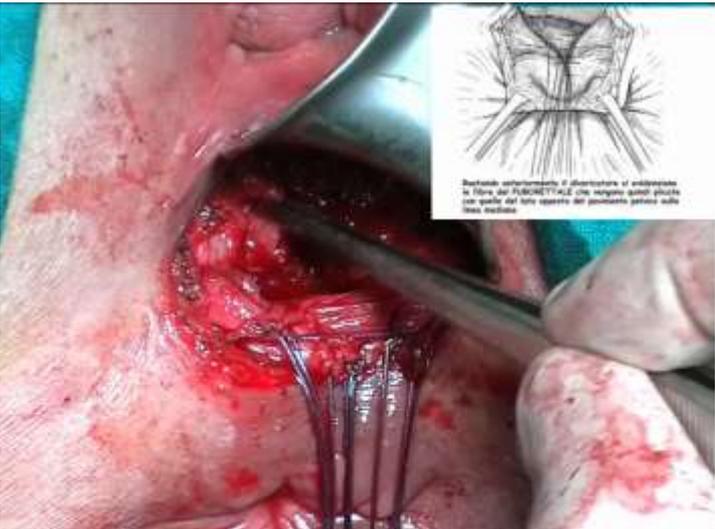
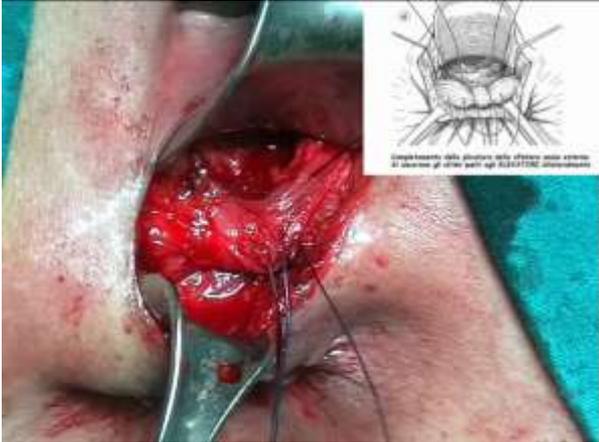
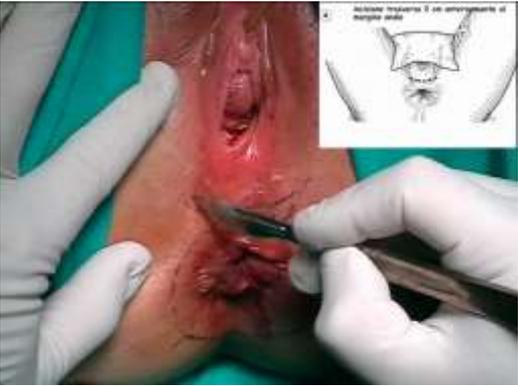
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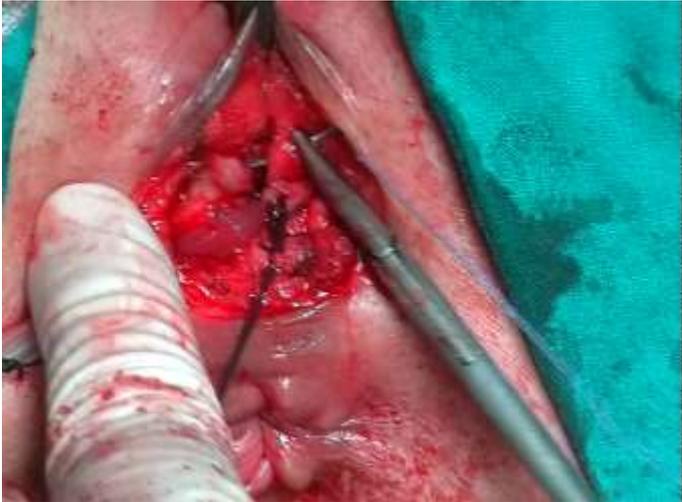
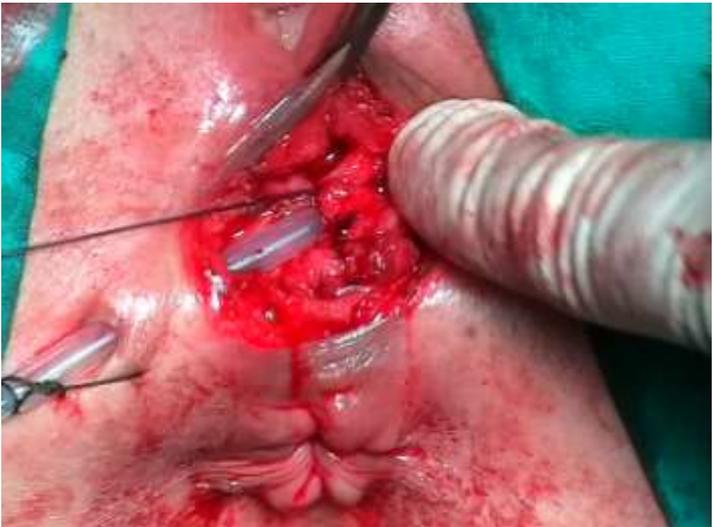
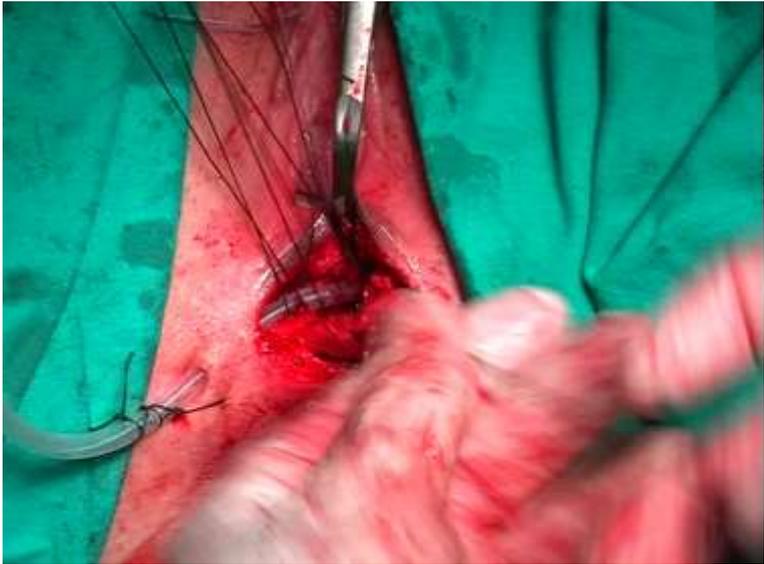
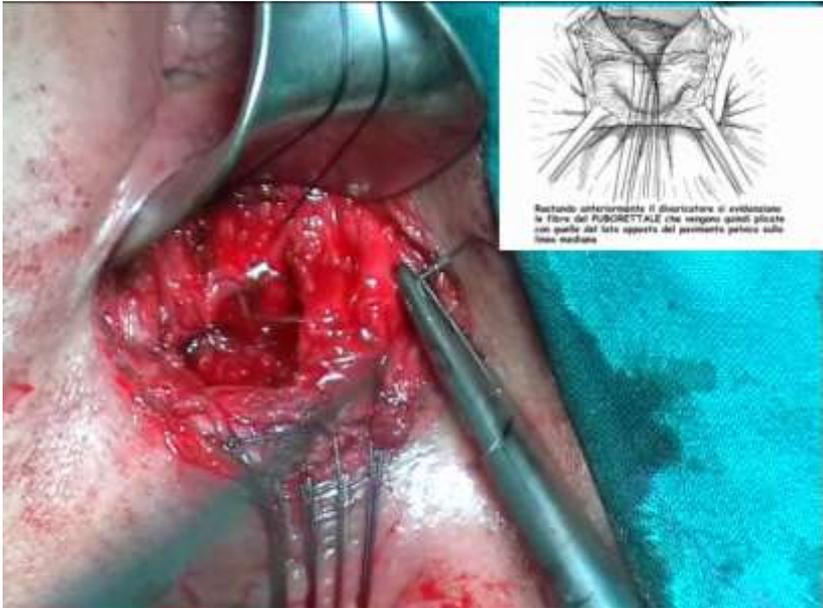
Schema elevatori dal perineo



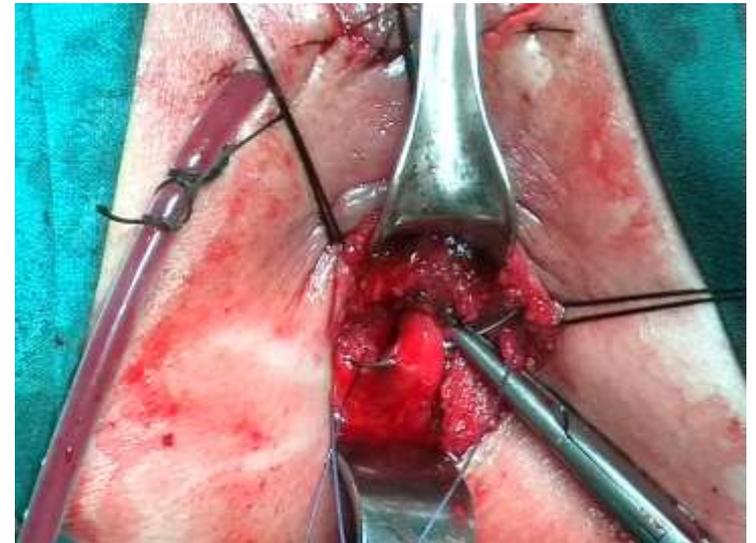
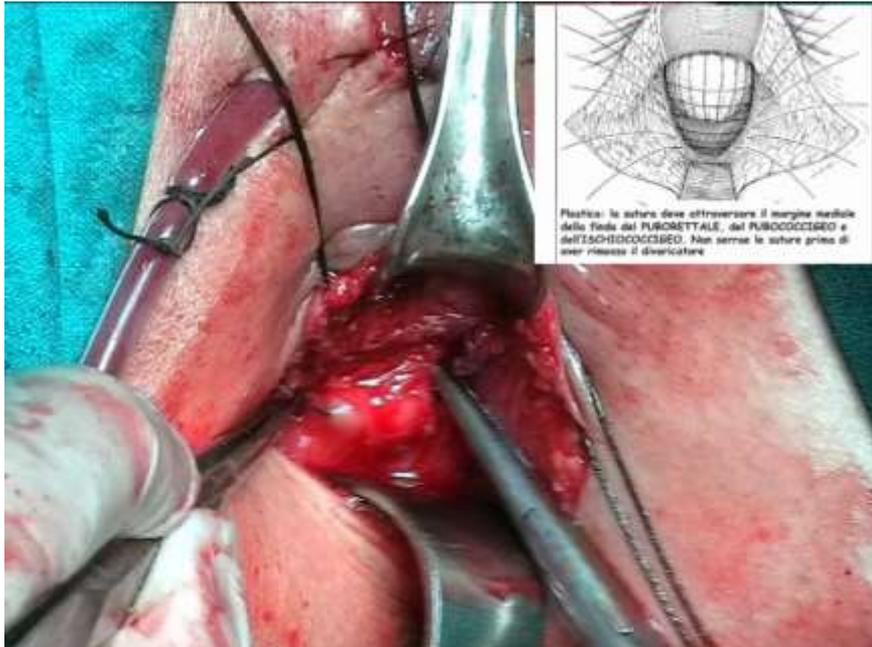
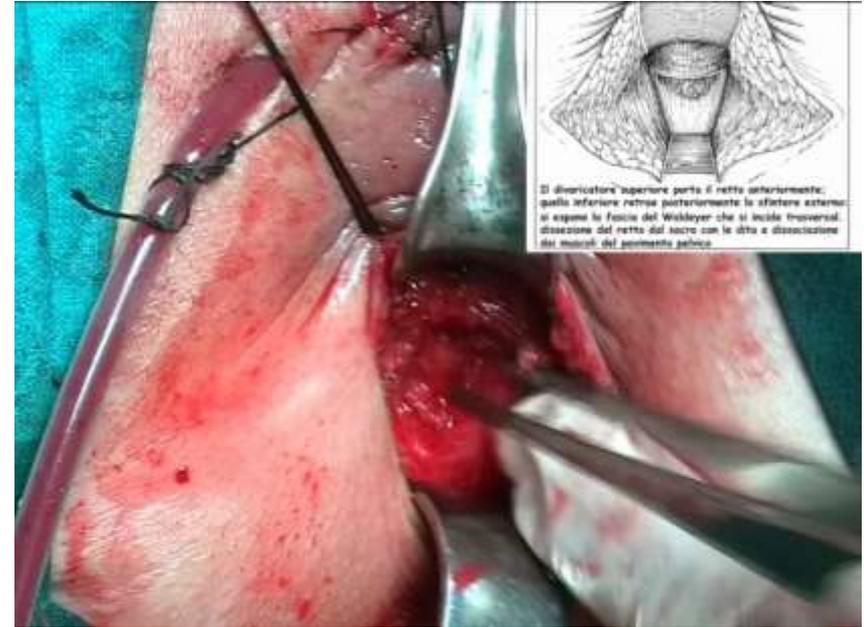
Total Pevic Floor Repair (1)



Total Pevic Floor Repair (2)



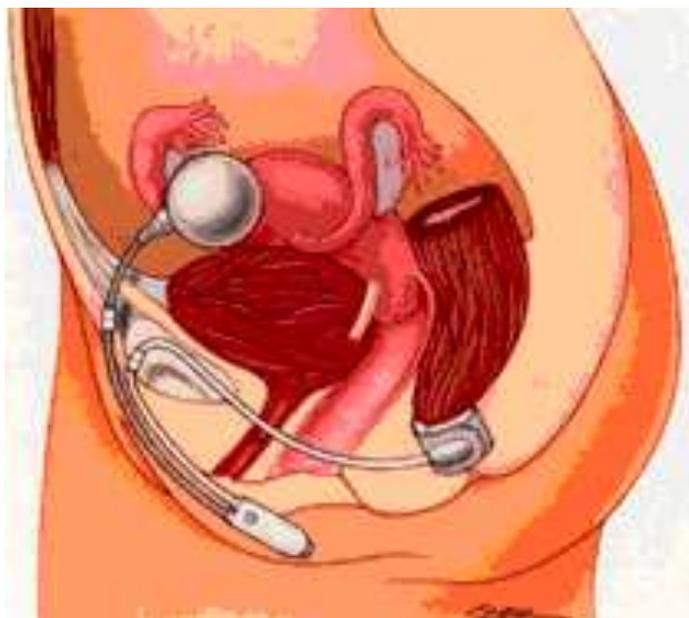
Total Pevic Floor Repair (3)



Artificial anal sphincter implantation

1 Guidance

- 1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
 - Audit and review clinical outcomes of all patients having artificial anal sphincter implantation.
- 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.
- 1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence.



2 The procedure

2.1 Indications

- 2.1.1 The causes of faecal incontinence are diverse. Existing treatment options include medical therapy, biofeedback techniques and surgery in selected patients. Surgical treatments include sphincter repair, sacral nerve stimulation, encirclement procedures and muscle transposition (for example, dynamic graciloplasty). Some patients may require a colostomy if other treatments fail.

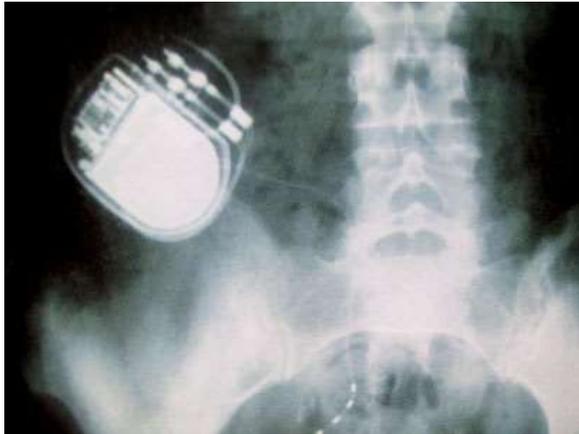
2.2 Outline of the procedure

- 2.2.1 Implantation of an artificial anal sphincter is used to treat severe faecal incontinence. In this procedure, a fluid-filled cuff is implanted around the anal canal. Tubing from the cuff is channelled under the skin of the perineum and connected to a control pump placed subcutaneously in the scrotum or labia. The control pump is connected by tubing to a pressure-regulating balloon implanted in the abdominal wall. The cuff simulates the natural function of the sphincter muscle: when the fluid is displaced from the cuff to the balloon via the patient-controlled pump, defaecation can take place. Once defaecation is complete, the fluid is slowly returned to the cuff and continence is again achieved. For more details, refer to the Sources of evidence (see overleaf).

Interventional Procedure Guidance 66

This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.



AUTHORS' CONCLUSIONS

Implications for practice

The limited evidence from the included studies suggests that permanent SNS can lead to significant improvement in continence in some (but not all) selected patients with severe faecal incontinence who have not responded to conservative treatment. This is reflected by a reduction in episodes of faecal incontinence and urgency and improvement in the ability to defer defaecation. However SNS is not effective for all patients with severe faecal incontinence and even some of those who meet the criteria to progress from temporary to permanent stimulation may then go on to experience an increase rather than a reduction in episodes of faecal incontinence. Therefore, while the practice of employing temporary, percutaneous stimulation for a two-to-three week period will identify those most likely to respond positively to a permanent implant, it will not identify all those for whom a permanent implant will not be beneficial. The adverse event rate leading to removal of the permanent stimulator was high at 15%.