Complications of pelvic floor reconstructive surgery using mesh

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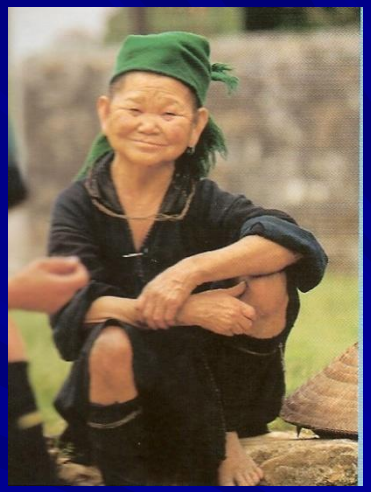
AGING POPULATION

I

IN THE FUTURE

18% MORE FEMALES > 75 y

38% MORE FEMALES > 80 y



2010 USA: COSTS FOR UI 26 BILIONS USD

PELVIC FLOOR RECONSTRUCTIVE SURGERY DILEMAS BEFORE TREATMENT

- Accurate patient assessment and appropriate decision making is crucial to optimal outcome
- Patient and surgeon may have different goals and expectations
- Surgery may not treat patient's symptoms
- Good primary surgery has the best outcome
- Unadequate surgery may result in
  - crippling complications
  - patient misery
  - patient anger
  - compromise further operations

PELVIC FLOOR RECONSTRUCTIVE SURGERY PROBLEMS TO SOLVE

- Overlap of POP and LUTS
- Evidence for urodynamic evaluation
- No optimal method for demasking incontinence
- No evidence for choice of treatment
- Relation of symptoms to anatomy & urodynamics
- Definition of POP

CONCLUSION?

- Do the best POP - procedure
- Do the best UI - procedure

Opinion of the old „masters“

K.Richter: „You know, most of the young collegues don‘t know anatomy any more, thus are unable to reconstruct it“

Journal of Pelvic Surgery
Vol. 4, No. 5, 201–203
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E.Kohorn

Editorial

The Gynecologic Surgery Imperative

To maintain adequate standards of care for women with pelvic floor dysfunction, the necessity for a subspecialty in urogynecology and reconstructive pelvic surgery has become inevitable. This is due to chronic neglect in the adequate teaching of this subspecialty in residency training programs and due to the failure of the leadership in obstetrics and gynecology in the United States to provide this important field with adequate academic identity.

WHAT SHOULD WE KNOW BEFORE DECIDING FOR SURGICAL TREATMENT

- Will patient quality of life be improved?
- Is patient prepared for surgical treatment?
- Which surgical procedure is most adequate for the patient?
- % efficiency of surgical procedure
- Safety
- Surgeon’s skill
- Price

PROBLEMS FACING PELVIC FLOOR RECONSTRUCTIVE SURGERY

11,1 % lifetime risk of having an operation for POP

High recurrence rate:

- Up to 30% of patients require repeat surgery
- Time intervals between procedures decrease with each successive repair

Olsen AL et al Obstet Gynecol 1997

- Up to 45% of patients developed recurrent cystourethrocele after anterior repair

Sand PK et al Am j Obstet Gynecol 2002

Richard TeLinde

(1894 - 1989)

America's famous gynecologic surgeon observed late in his career: every honest surgeon of extensive and long experience will have to admit that he is not entirely and absolutelly satisfied with his long term results of all his operations for prolapse and allied conditions. (1966)

NEW TRENDS IN THE PELVIC RECONSTRUCTIVE SURGERY

- Simple procedure
- Few intraoperative complications
- No postoperative troubles
- Short hospitalisation
- High cure rate
- Favourable long-term results
- Prosthetic Materials

INDICATION FOR MESH USE

- Previous failures, recurrence after hysterectomy
- Primary repair in severe defects
- Older sexually inactive patients
- Patients at high risk for failure (patients exposed to heavy work – lifting)

[1] Davila et al. *Int Urogyn J 2006;17(1):S51-55*

SURGICAL STRATEGIES IN PELVIC FLOOR RECONSTRUCTION

anterior compartment

anterior reconstruction / paravaginal repair

in case of recurrencies – use mesh or graft ?

mid compartment

(vaginal hyst.) + sacrospinous /sacrotuberous fixation

in case of recurrency use mesh or graft or abdominal route ?

posterior compartment

posterior reconstruction , rectopexy, anal sphincter repair

WHICH MESH ?

- Most currently used meshes are too “heavyweight” (over dimensional and inflexible)
- Monofilament meshes better than multifilament
- Less foreign body reaction with monofilament meshes
- Optiminal pore size > 75 µm
- User friendly (easy to handle)
- Minimal shrinkage and folding

Currently there is a real dilemma that the widespread introduction of many new procedures and devices in urogynaecological practice is Marketing rather than Evidence Based

STUART STANTON UK

PROBLEMS OF MESHES

- human experimentation
- short follow-up
- expert opinion mostly
- **company driven medicine**
- research based on clinical trials
- lack of RCT

"Given the limited data…..with regard to type of mesh material….associated with postoperative risks, especially mesh erosion, the procedures should be considered experimental…."

ACOG Practice Bulletin, Feb. 2007

"Given the limited data…..with regard to type of mesh material….associated with postoperative risks, especially mesh erosion, the procedures should be considered experimental…..
patients should consent to surgery with an understanding of postoperative risks and complications, and lack of long term data."

ACOG Practice Bulletin, Sept. 2007

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

Databases on the FDA Website

Market data from manufacturers indicate that in 2010 approximately 300,000 women underwent surgical procedures in the United States to repair POP and approximately 260,000 underwent surgical procedures to repair SUI. According to industry estimates, approximately one out of three POP surgeries used mesh, and three out of four of the mesh POP procedures were done transvaginally. For SUI surgeries, over 80 percent were done transvaginally with mesh.

Databases on the FDA Website

III. SUMMARY OF ADVERSE EVENT REPORTS

The FDA conducted a search of the Manufacturer and User Device Experience (MAUDE) database for medical device reports (MDRs) of adverse events associated with all urogynecologic surgical mesh products received from January 1, 2005 - December 31, 2010. The search identified 3,979 reports of injury, death, and malfunction. Among the 3,979 reports, 2,874 reports were received in the last 3 years (January 1, 2008 - December 31, 2010), and included 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. The number of MDRs associated with POP repairs increased by more than 5-fold compared to the number of reports received in the previous 3 years (January 1, 2005 - December 31, 2007).

Databases on the FDA Website

FDA proposes to reclassify surgical mesh for transvaginal POP

On April 29th 2014, the U.S. Food and Drug Administration issued two proposed orders to address the health risks associated with surgical mesh used for transvaginal repair of pelvic organ prolapse (POP). If finalized, the orders would reclassify surgical mesh for transvaginal POP from a moderate-risk device (class II) to a high-risk device (class III) and require manufacturers to submit a premarket approval (PMA) application for the agency to evaluate safety and effectiveness. The FDA will take comments on the proposed order for 90 days.

J&J Ordered to Pay $5.7 Million Over Incontinence Implant

J&J, based in New Brunswick, New Jersey, faces more than 30,000 lawsuits accusing Ethicon of making improperly designed vaginal inserts that damaged women's organs and made sex painful.

The verdict is the first to find fault with the Abbrevo sling, which J&J introduced in 2010 as its latest innovation for treating incontinence in women. Analysts say the market for such devices is expected to top $1.7 billion by 2017.

ARE MESHES REALLY NECESSARY ?

BJOG: an International Journal of Obstetrics and Gynaecology
January 2005, Vol. 112, pp. 107–111

DOI: 10.1111/j.1471-0528.2004.00332.x

Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh

Rodolfo Milani,[a] Stefano Salvatore,[a] Marco Soligo,[a] Paola Pifarotti,[b] Michele Meschia,[b] Marina Cortese[a]

Objective To evaluate the effects of prolene mesh on urinary, bowel and sexual function in prolapse surgery.

Design Prospective observational study on consecutive women.

Setting Two referral uorgynaecological units in Italy.

Population Women requiring prolapse repair for anterior or posterior vaginal prolapse.

Methods All women were assessed for urinary, bowel, prolapse symptoms and dyspareunia pre- and post-

Conclusions Although this study shows good anatomical results with the use of prolene mesh for prolapse repair, there was a high rate of morbidity. We believe that the use of prolene mesh should be abandoned.

Results We recruited 63 women (mean age 63 years) with a mean follow up of 17 months. Anatomically, the success rate was 94%. Thirty-two women had an anterior repair. Among this group, the sexual activity rate did not alter but dyspareunia increased by 20%. Urge and stress incontinence did not change post-operatively but urgency improved in 10% and 13% had vaginal erosion of the mesh. Thirty-one women had a posterior repair. Among this group, sexual activity decreased by 12% and dyspareunia increased in 63%. Constipation improved in 15% and anal incontinence in 4%, and 6.5% of women had vaginal erosion of the mesh and one required mesh removal for pelvic abscess.

Conclusions Although this study shows good anatomical results with the use of prolene mesh for prolapse repair, there was a high rate of morbidity. We believe that the use of prolene mesh should be abandoned.

PELVIC FLOOR RECONSTRUCTIVE SURGERY TECHNICAL POINTS TO DISCUSS

- Anaesthesia : local, regional (spinal), general
- Installation:
    - retropubic: thights flexion <60°
    - obturator: hyper flexion >100 ° and abduction
- Infiltration & hydro dissection (with or without local anaesthesia)
- Full or empty bladder
- Landmarks or not
- Needle tip control
- Cough stress test
- Cystoscopic control
    - -70° lens
    - Not mandatory for obturator (but if cystocele present)
- Foley catheter and vaginal packing
- Concomittant gycologic or reconstructive surgery

BUT :

- Review manufacturers information
- Attend accredited theoretical course
- See ‘X’ number of procedures
- Supervised for ‘Y’ number procedures
- Discuss experience with patient
- Audit my results

MOST FREQUENT COMPLICATIONS REPORTED TO THE FDA

- Vaginal mesh erosion (also called exposure, extrusion or protrusion)
- Pain (including painful sexual intercourse known as dyspareunia)
- Infection
- Urinary problems
- Bleeding
- Organ perforation
- There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage and emotional problems

DEATH REPORTS ASSOCIATED WITH MESH PROCEDURES

- Three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforations, one hemorrhage)

- Four deaths were due to post-operative medical complications not directly related to the mesh placement procedure.

VAGINAL EROSIONS

- IUGA and ICS working group on Complication Terminology recommend abandoning the term “erosion” and replacing with new terms:
- Exposure: A condition of displaying, revealing, exhibiting or making accessible
- Extrusion: Passage gradually out of a body structure or tissue

DOI: 10.1111/j.1471-0528.2007.01558.x
www.blackwellpublishing.com/bjog

Urogynaecology

Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse

M Abdel-fattah, I Ramsay on behalf of the West of Scotland Study Group*

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Email mohamed.abdelfattah@sgh.scot.nhs.uk

289 women (219 Gynecare, 70 AMS)

Bladder injury	1.6 %
Rectal injury	1.1 %
Serious vascular injuries	2
Buttock pain	5.2 %
Vaginal erosion	10.0 %
Bladder erosion	1
Serious infection	2

Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair

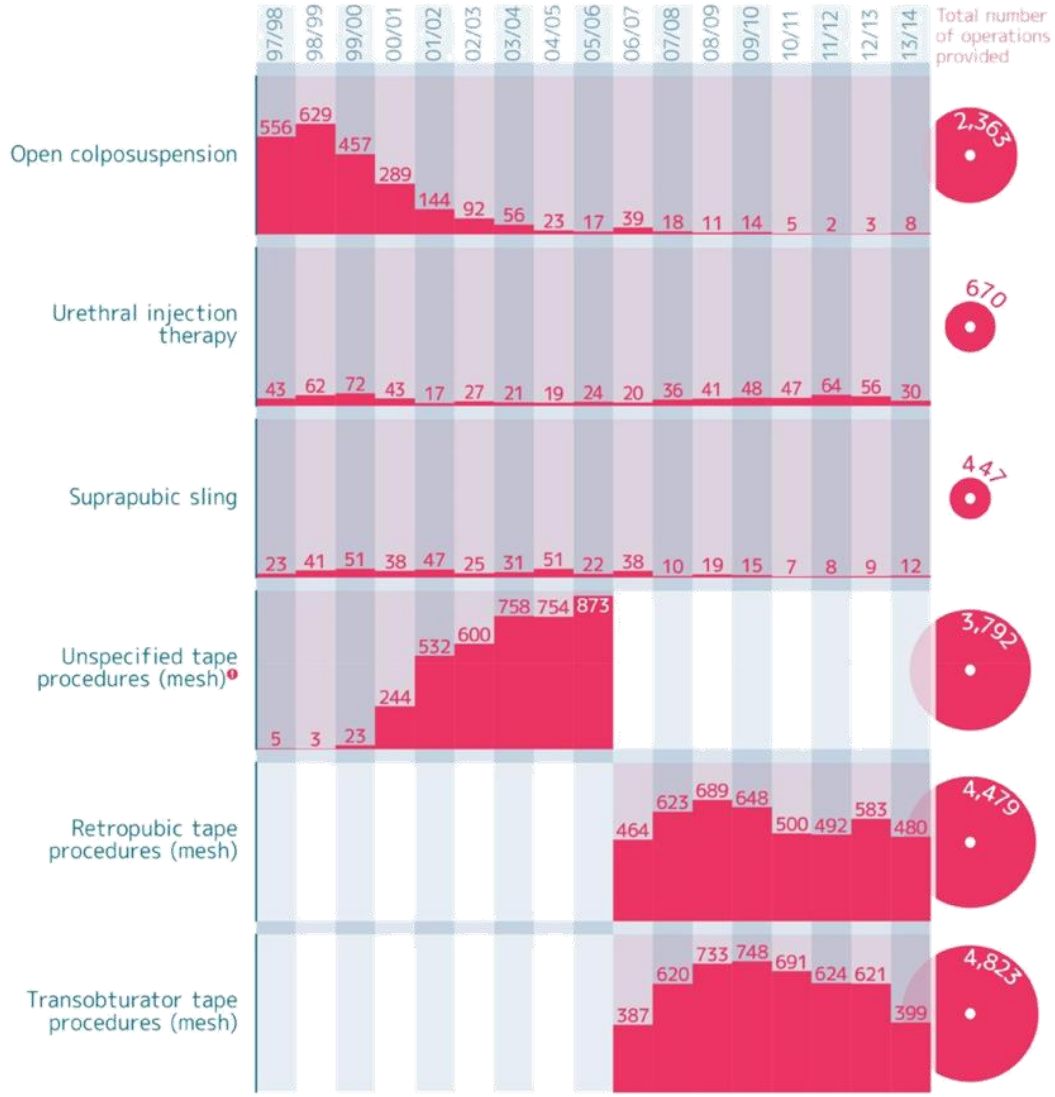
*Daniel Altman, MD, PhD, and Christian Falconer, MD, PhD, for the Nordic Transvaginal Mesh Group**

Obstet Gynecol 2007;109:303–8

248 women (Prolift)

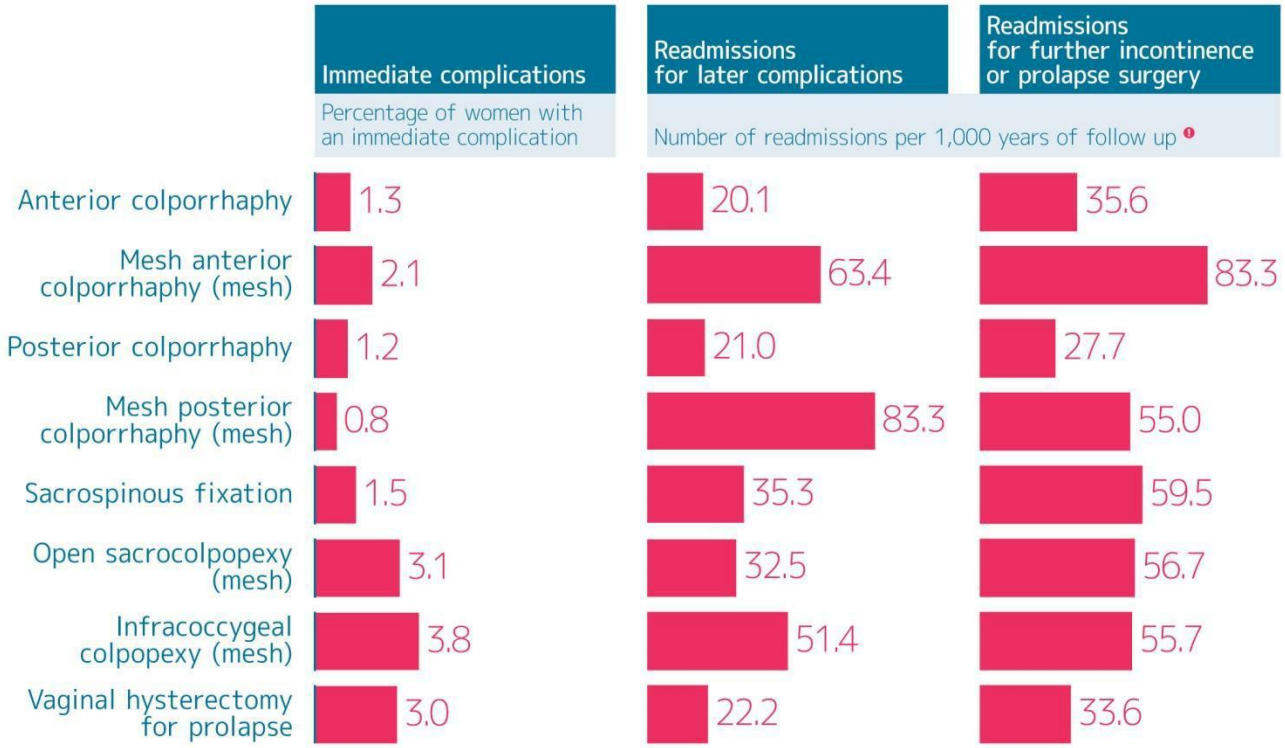
Major complications	11 (4.4%)
Bladder perforation	5
Urethra perforation	1
Rectal perforation	4
Bleeding >1000ml	1
Minor complications	36 (14.5%)
UTI	16
Urinary retention	4
Fever	4

Numbers of first, single operations for stress urinary incontinence by year

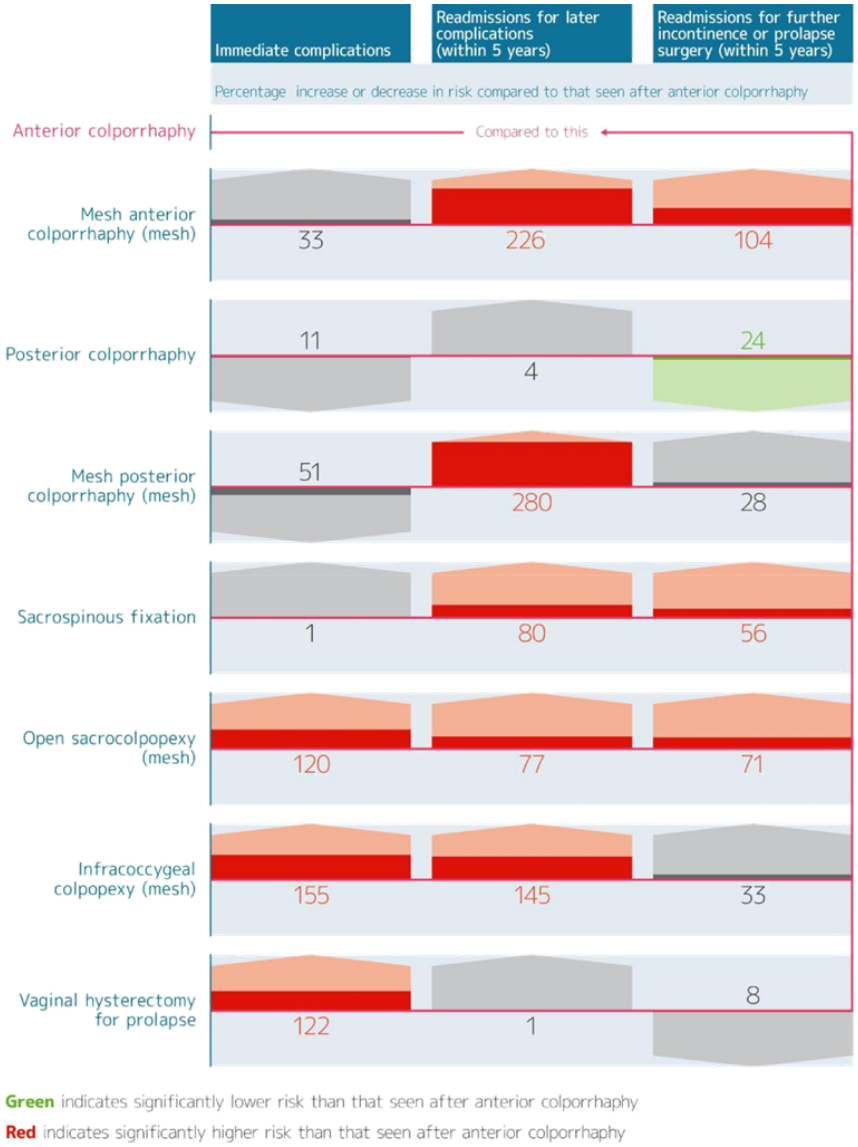


Operations provided during a patient's admission to hospital are recorded on routine hospital discharge records using OPCS Classification of Interventions and Procedures codes. Between 1997/98 and 2005/06, the codes available did not specify which kind of tape operation had been provided. After April 2006, new codes allowed the particular type of tape operation (retropubic or transobturator) to be recorded.

The risk of developing problems after the different types of pelvic organ prolapse operation included in the analysis is shown below.



This is the total number of readmissions that would occur on average if 200 women were each monitored for five years after having their pelvic organ prolapse operation.


Immediate complications
Readmissions for later complications (within 5 years)
Readmissions for further incontinence or prolapse surgery (within 5 years)
Percentage increase or decrease in risk compared to that seen after anterior colporrhaphy
Anterior colporrhaphy
Compared to this
Mesh anterior colporrhaphy (mesh)
33
226
104
Posterior colporrhaphy
11
4
24
Mesh posterior colporrhaphy (mesh)
51
280
28
Sacrospinous fixation
1
80
56
Open sacrocolpopexy (mesh)
120
77
71
Infracoccygeal colpopexy (mesh)
155
145
33
Vaginal hysterectomy for prolapse
122
1
8
Green indicates significantly lower risk than that seen after anterior colporrhaphy
Red indicates significantly higher risk than that seen after anterior colporrhaphy

EROSIONS

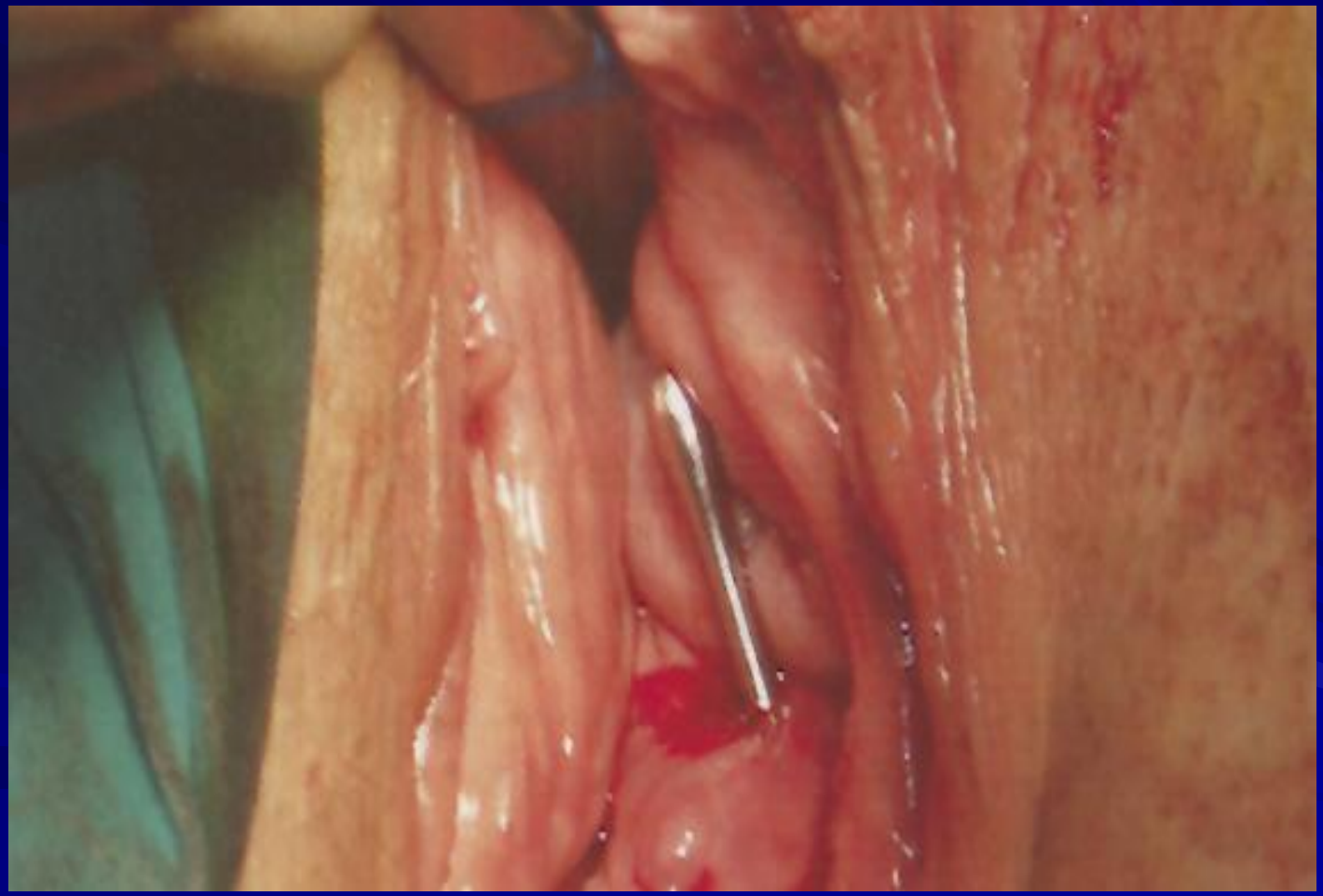
- *110 studies, 11785 patients (Systematic review in Medline of reports published between 1950 – november 2010:
  - 10.3% (95% CI, 9.7 – 10.9%, range 0 – 29.7%)
  - 6 weeks – 12 months after operation

Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG(2011)(Systematic Review Group of the Society of Gynecologic Surgeons)
Incidence and management of graft erosions, wound granulations, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J 22: 789 - 798

EROSIONS

- Risk factors:
  - concomitant hysterectomy
  - patients age
  - surgeon experience
  - use of inverted “T” colpotomy incision
  - Smoking
  - Diabetes mellitus

DEFECT

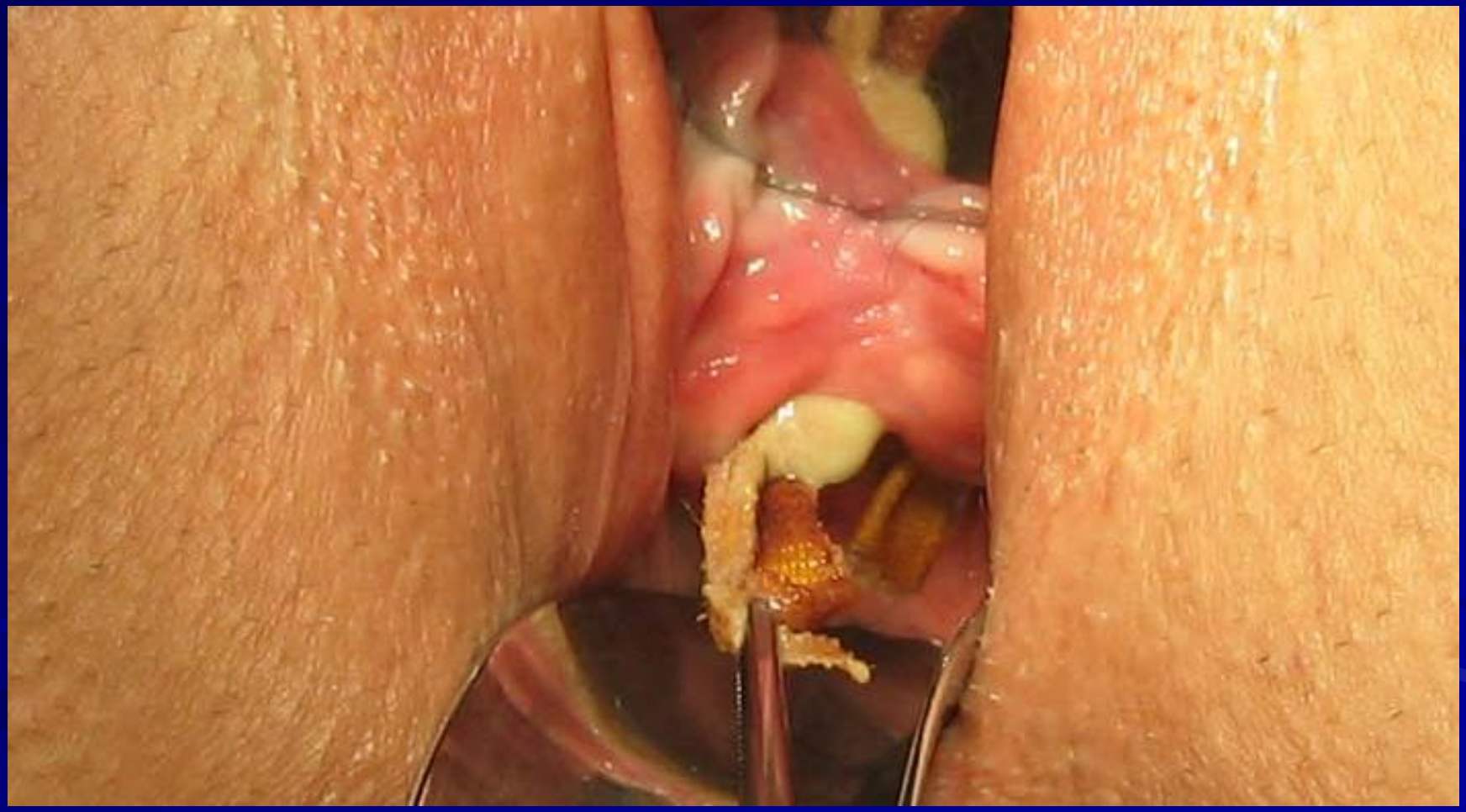


DEFECT

Gluteal hematoma after Apogee®

PROTRUSION

PROTRUSION (INFECTED)



GRANULATION

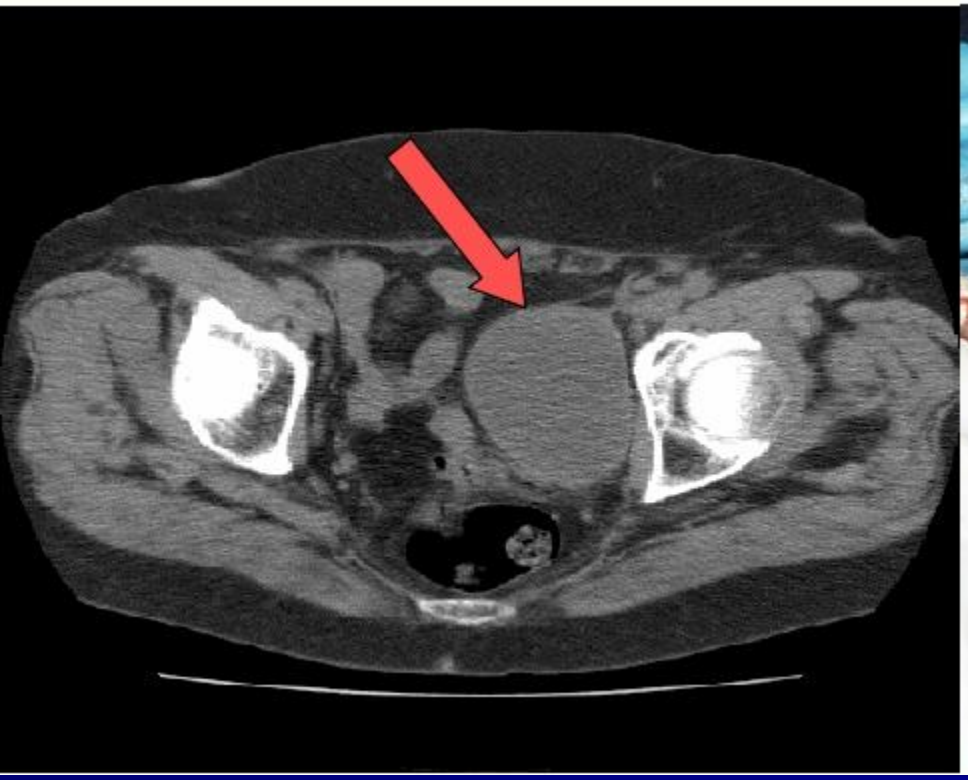
Int Urogynecol J (2005) 17: 3–13
DOI 10.1007/s00192-005-1331-4

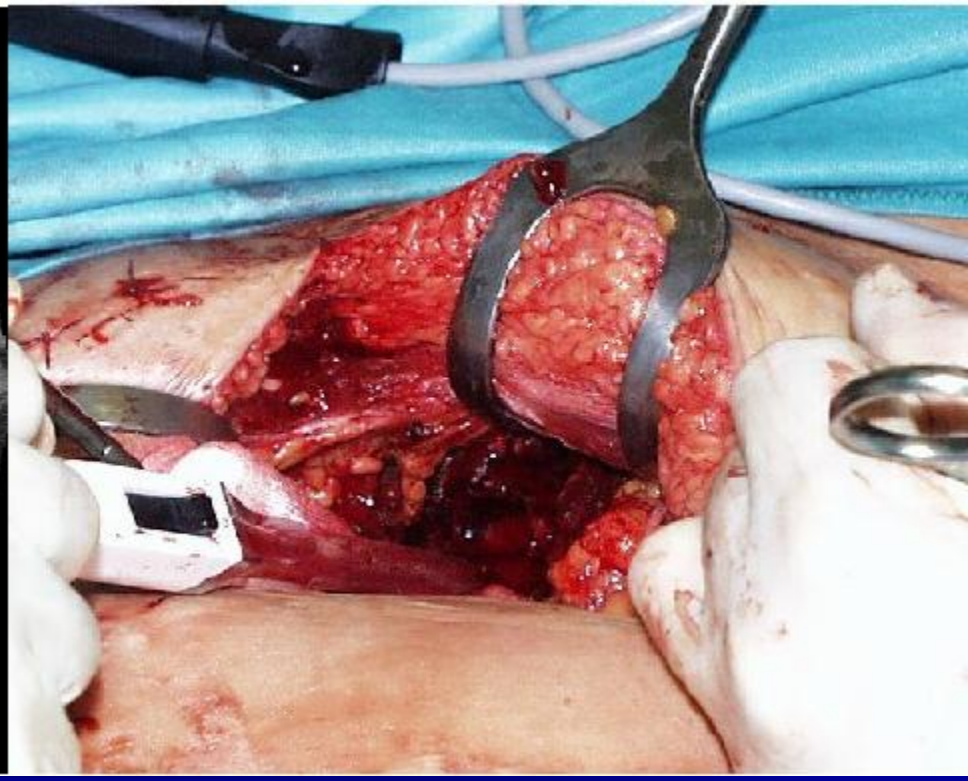
ORIGINAL ARTICLE

Eckhard Petri · Ruediger Niemeyer · Alois Martan
Ralf Tunn · Gert Naumann · Heinz Koelbl

Reasons for and treatment of surgical complications with alloplastic slings

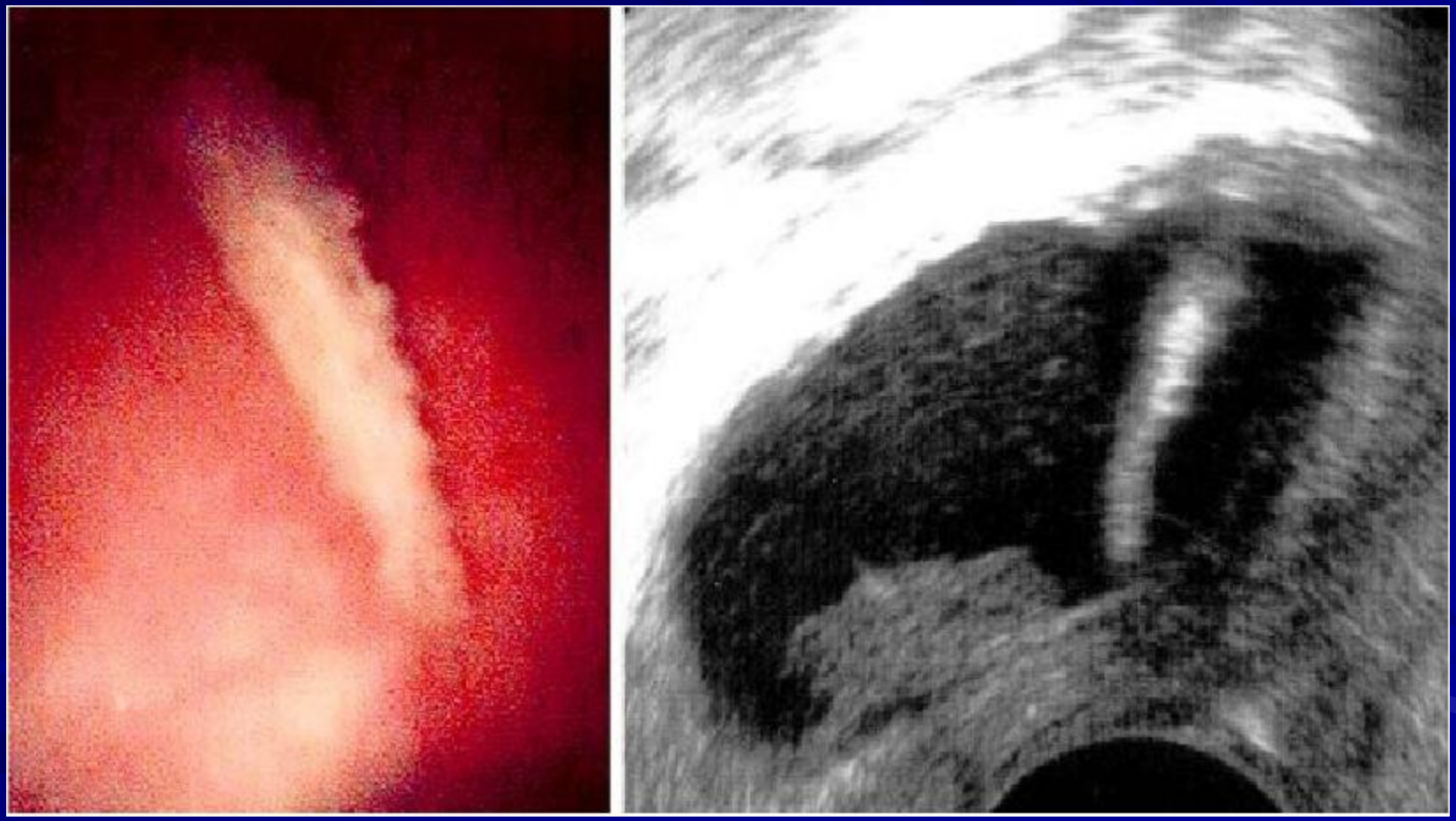
RETROPUBIC HEMATOMA





BLADDER PERFORATION

TAPE EROSION INTO BLADDER

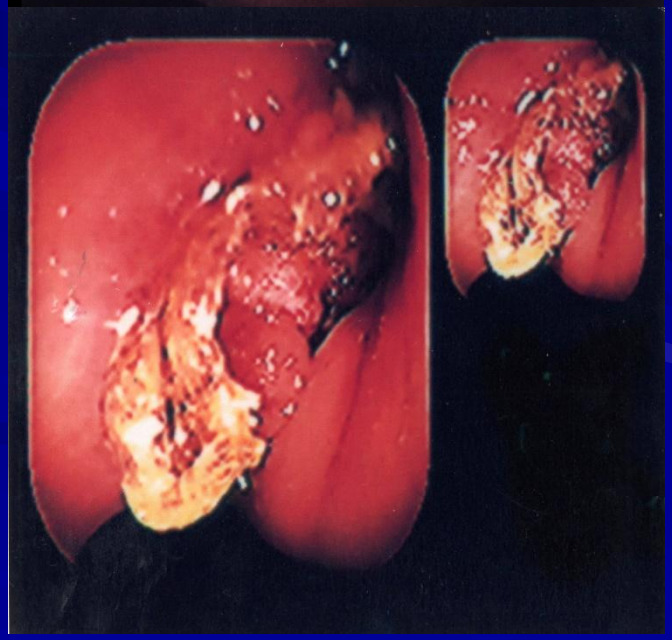


Petri et al IUJ 2006

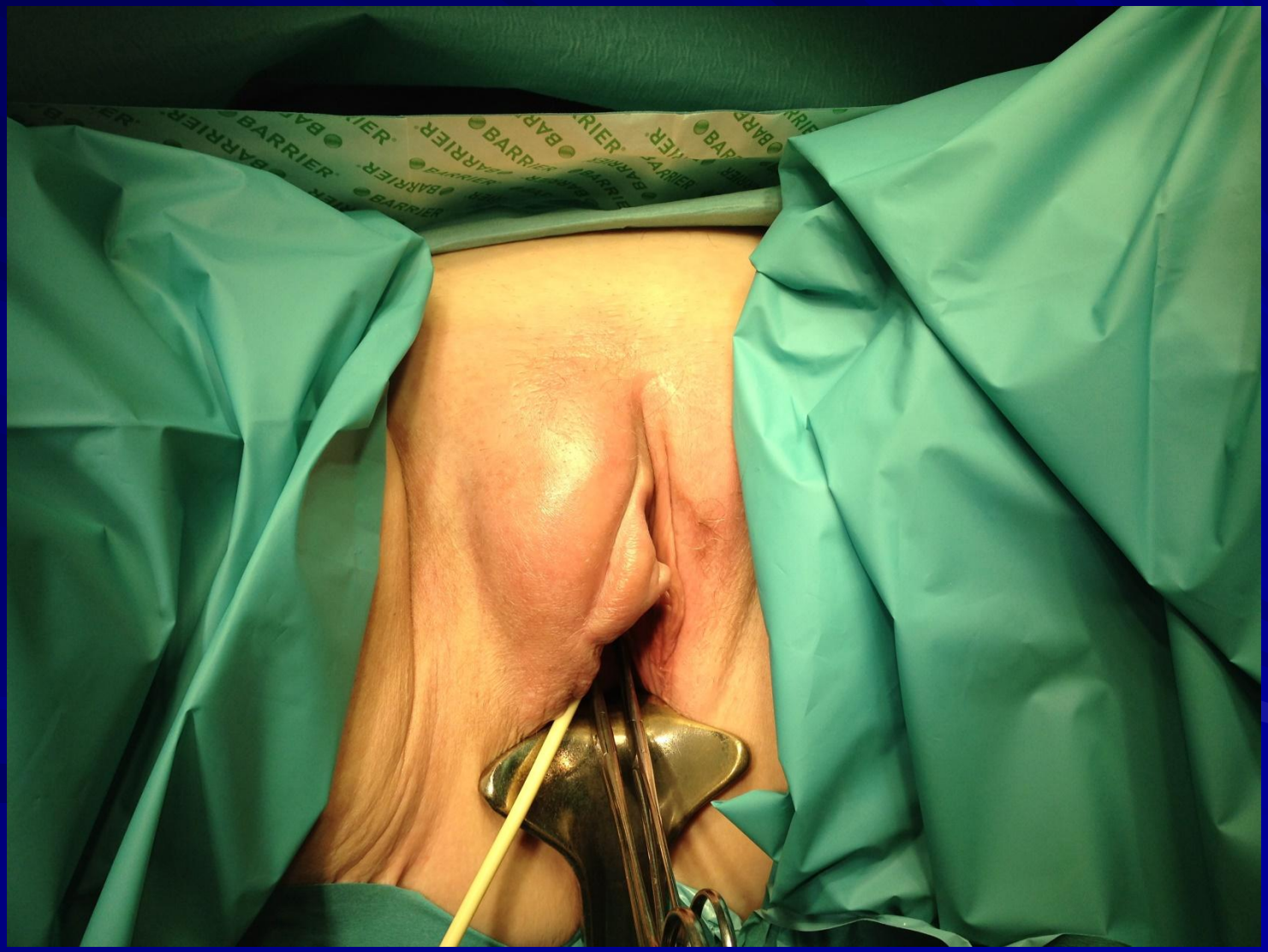
EXTRUSION OR EROSION

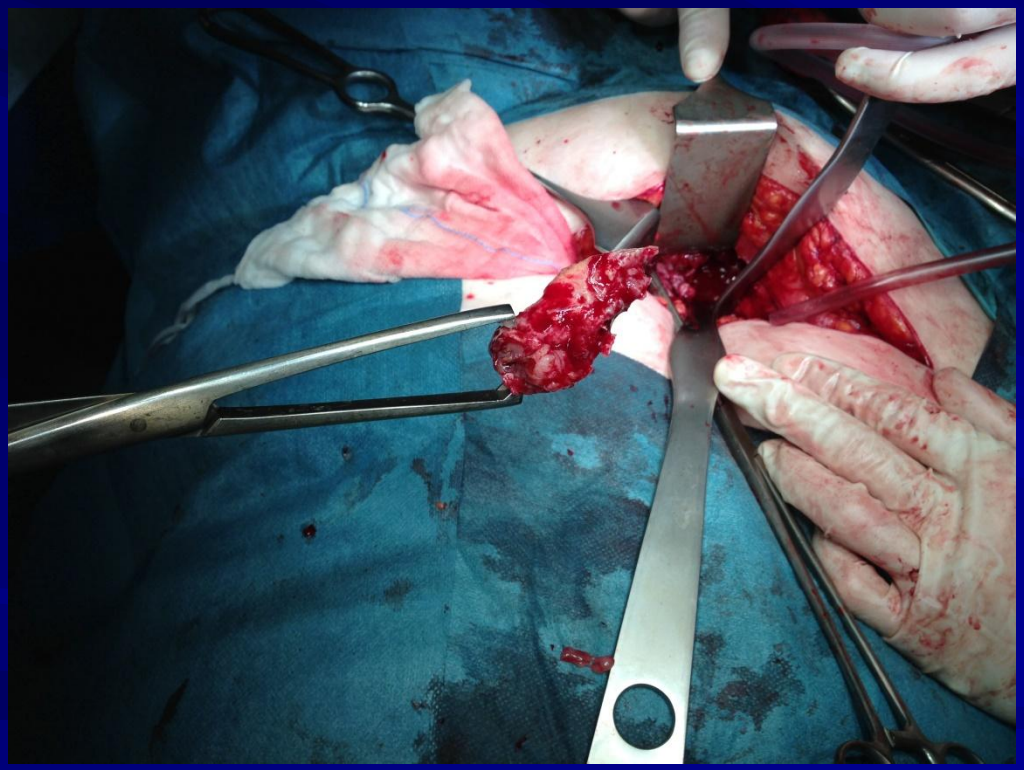
Increased with :

- Infection
- Prosthetic type
- Vaginal incision
- Prosthetic tension
- Tissue integrity
- Placement depth

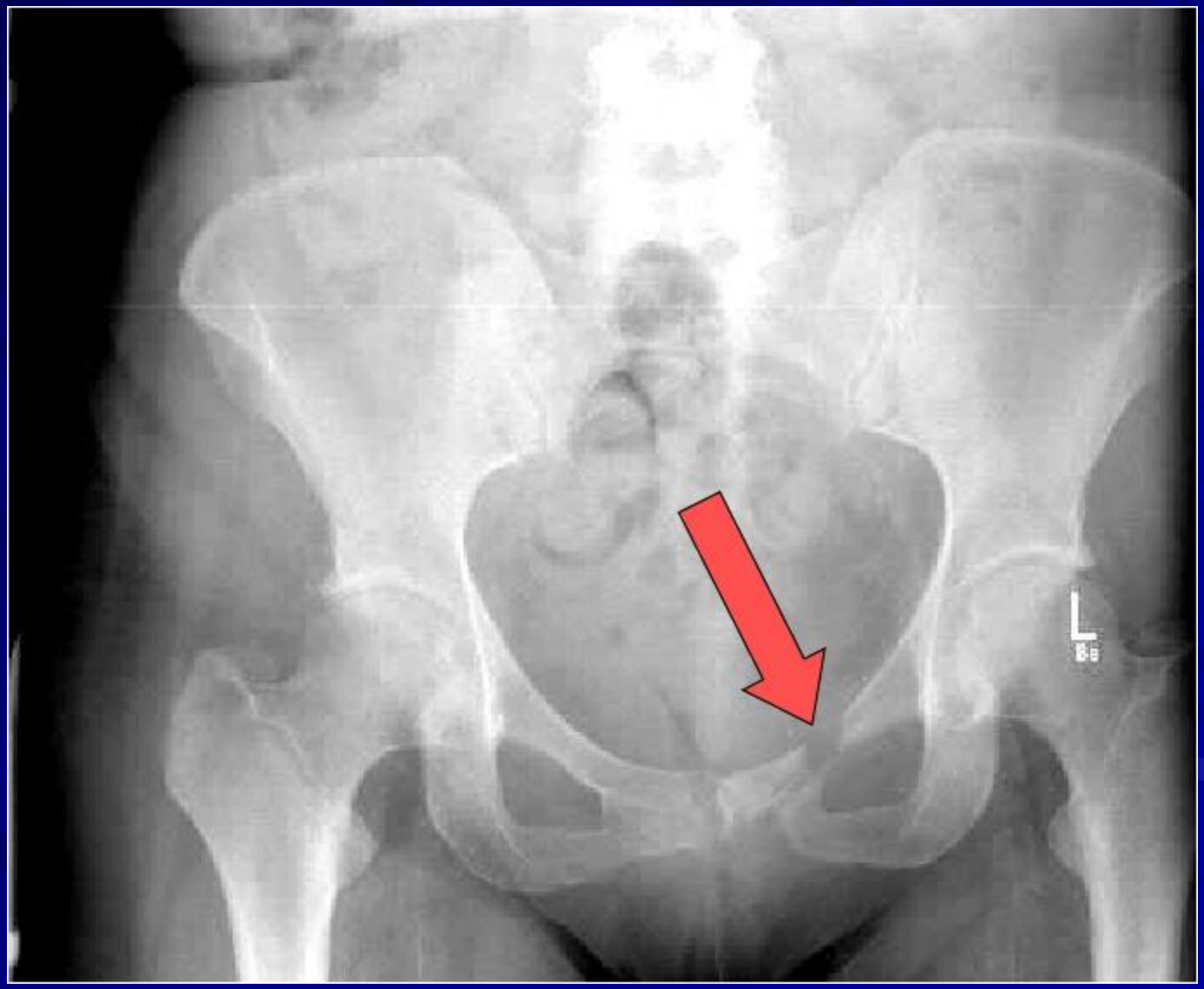


PREPUBIC ABSCESS AFTER RETROPUBIC SLING





NECROTIZING OSTEOMYELITIS AFTER TVT

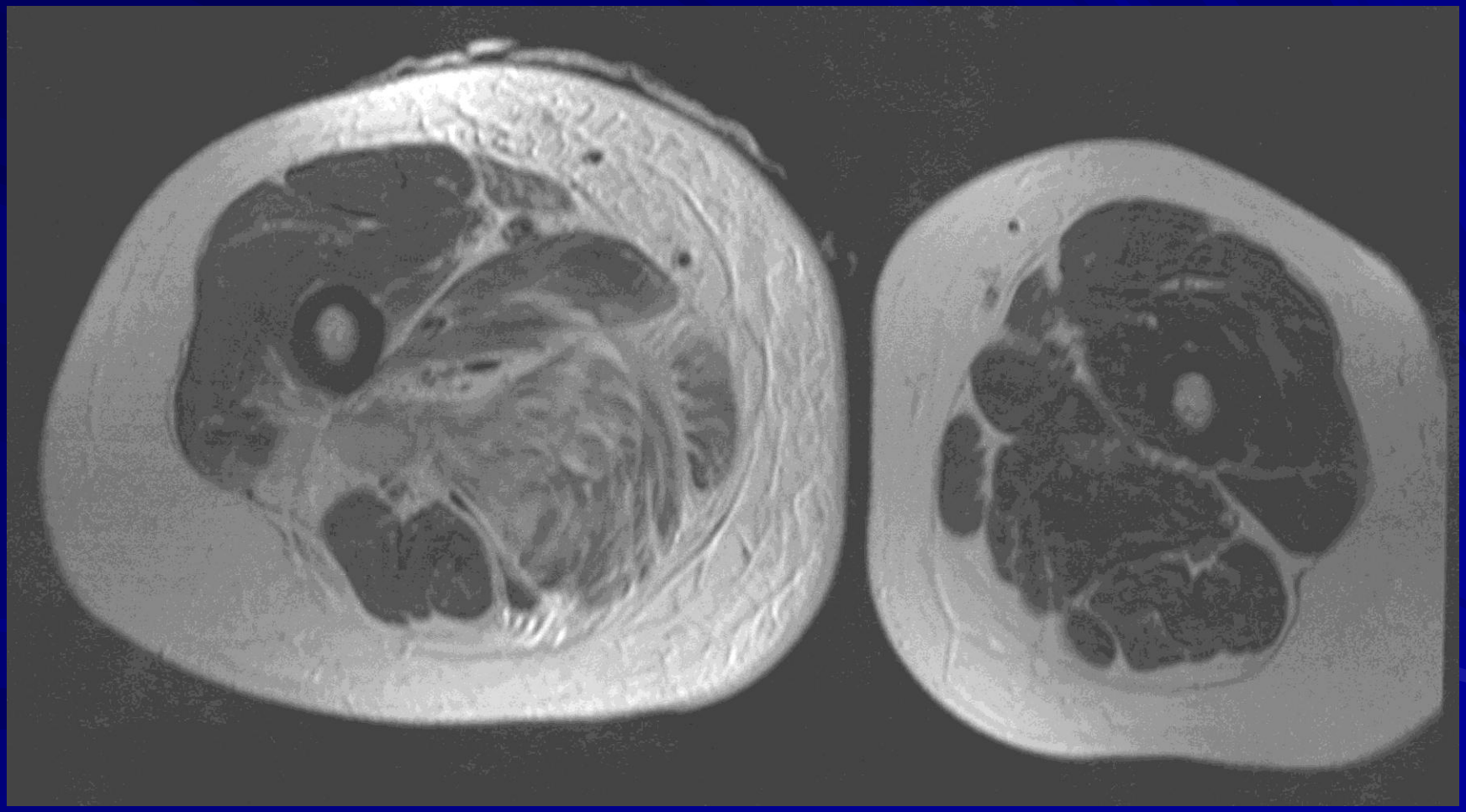


Courtesy H. Koelbl Mainz

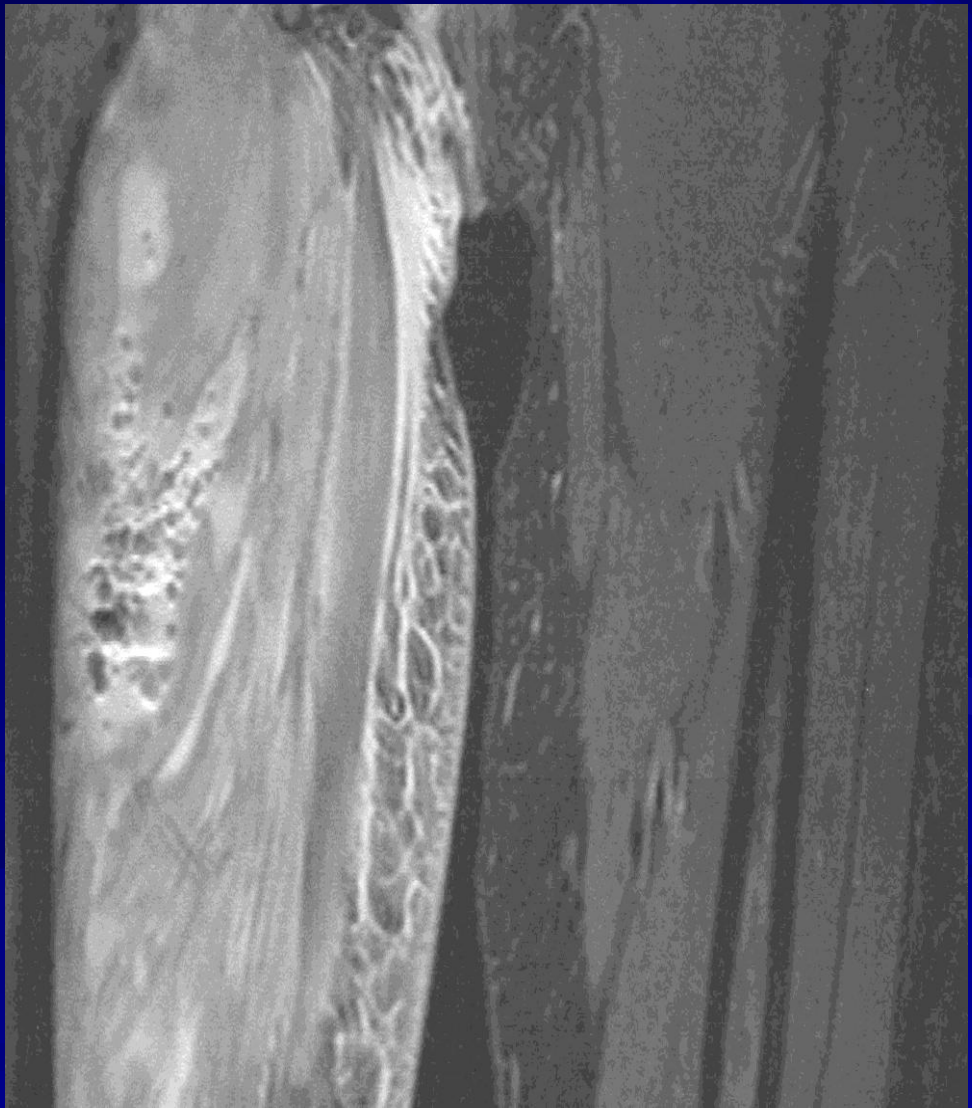
THIGH ABSCESS AFTER TRANSOBTURATOR TAPE

THIGH ABSCESS AFTER TRANSOBTURATOR TAPE

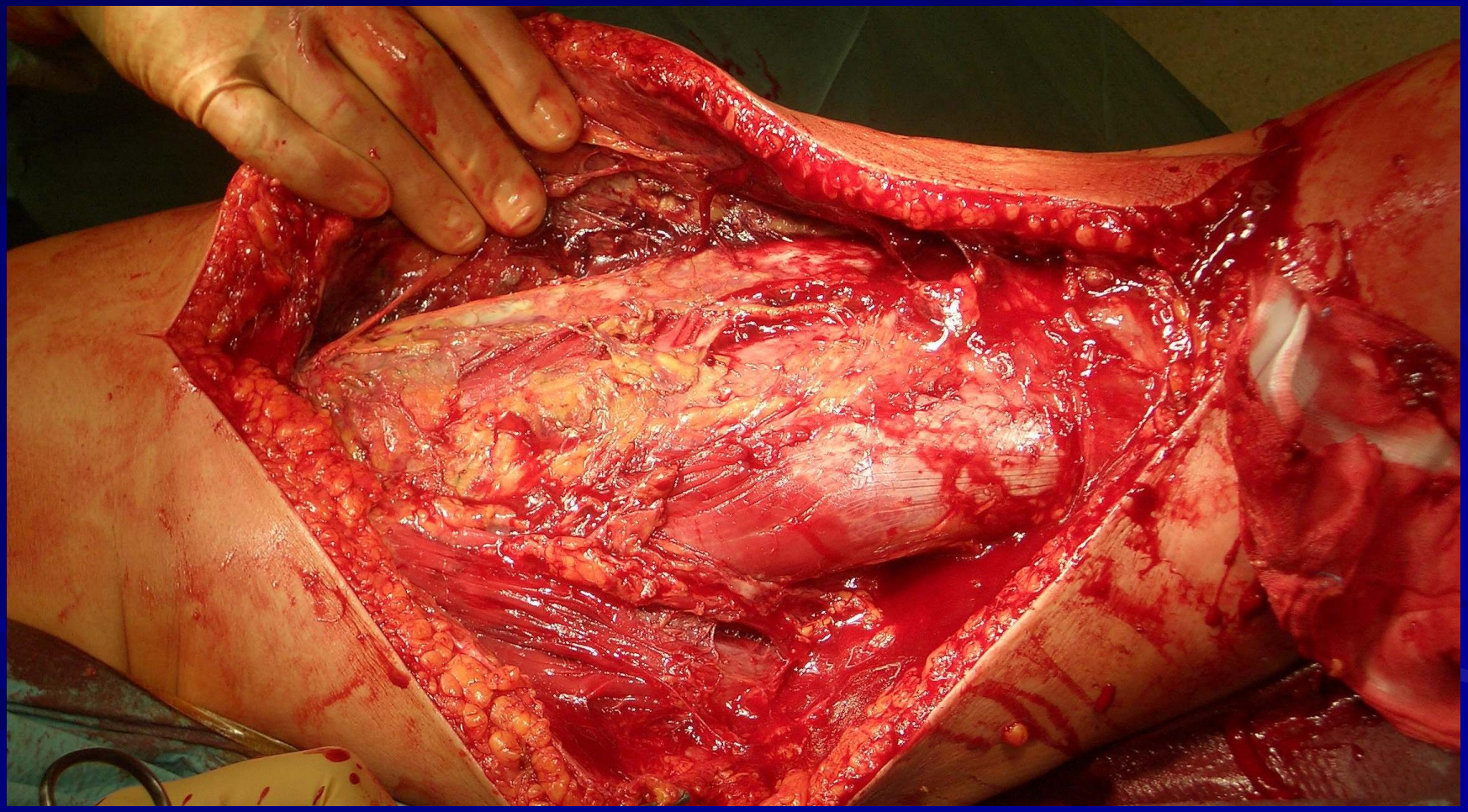
NECROTISANT FASCIITIS



NECROTISANT FASCIITIS



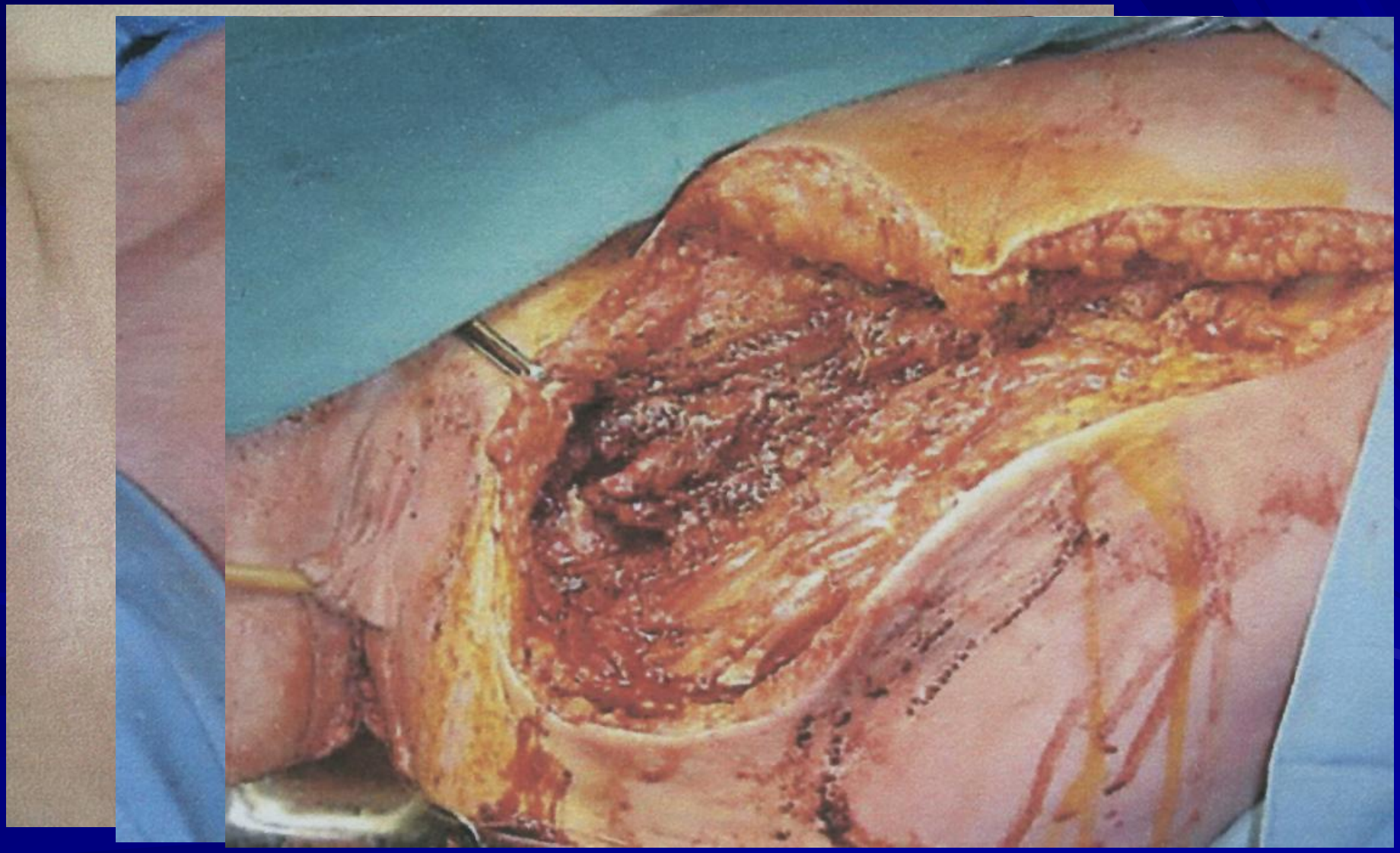
NECROTISANT FASCIITIS

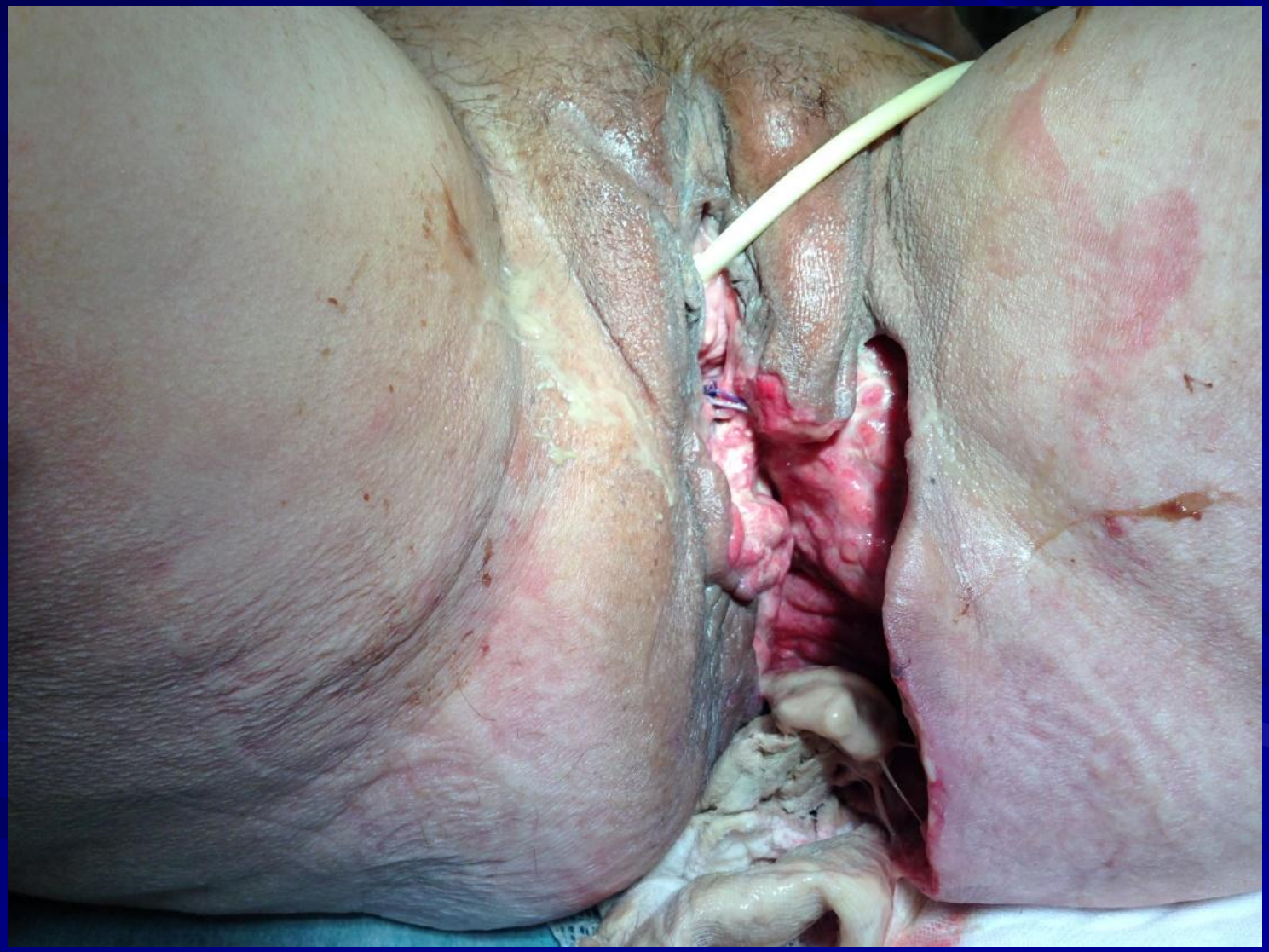


EXCISED TAPE

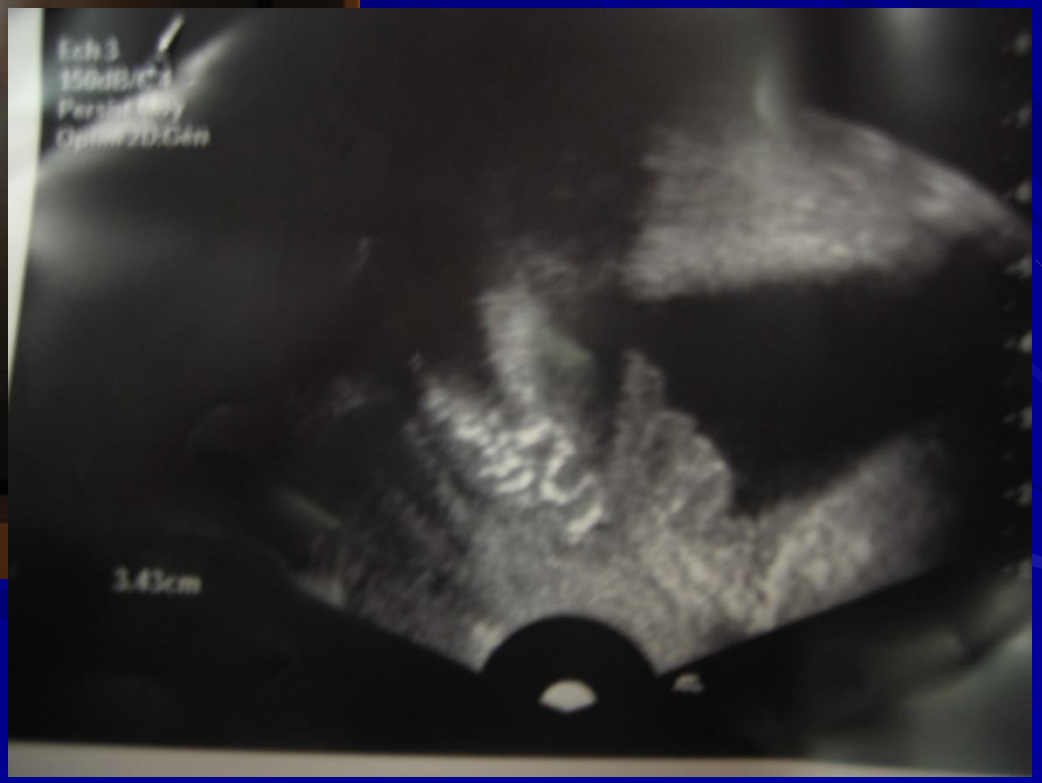
Fournier‘s gangrene – necrotisizing fasciitis

Karsenty et al. 2006 Int.Urogynecol.J.





Mesh shrinking



„Sometimes the surgeon is much more satisfied with his procedure than the patient ... „

Oscar Witzel 1903

We have to talk about definitive colostomies,
urinary diversions, complete loss of a functional vagina,
severe infections, sepsis, necrotisizing fasciitis ...

Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair

*Daniel Altman, MD, PhD, and Christian Falconer, MD, PhD, for the Nordic Transvaginal Mesh Group**

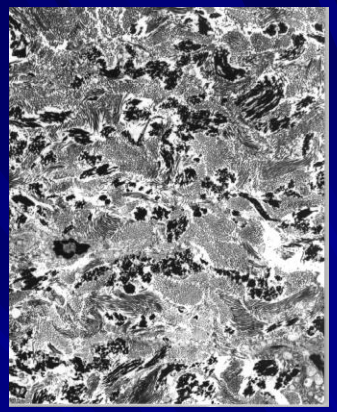
Serious : 4,4%
Minor : 14,5%

Table 2. Perioperative Complications

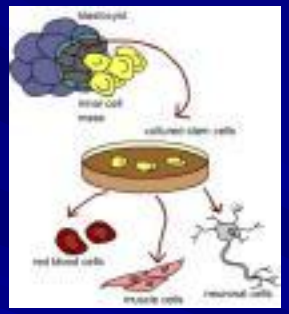
	Anterior Transvaginal Mesh Repair (n=106)	Posterior Transvaginal Mesh Repair (n=71)	Combined Anterior and Posterior Transvaginal Mesh Repair (n=20)	Total Transvaginal Mesh Repair (n=51)
Intraoperative complications				
Bladder perforation	2 (2)	0	1 (5)	2 (4)
Urethra perforation	1 (1)	0	0	0
Rectal perforation	0	3 (4)	1 (5)	0
Bleeding greater than 500 mL	3 (3)	1 (1)	0	3 (6)
Bleeding greater than 1,000 mL	1 (1)	0	0	0
Postoperative complications				
Urinary tract infection	6 (6)	3 (4)	0	7 (14)
Urinary retention	0	1 (1)	1 (5)	2 (4)
Catheterization during hospital stay	0	1 (1)	1 (5)	2 (4)
Anemia (hemoglobin less than 100 g/L)	1 (1)	0	0	0
Blood transfusion	1 (1)	0	0	0
Fever (more than 37.8° C)	2 (2)	0	0	2 (4)
Groin pain	1 (1)	1 (1)	0	0
Buttock pain	0	0	0	0
Vaginal hematoma	2 (2)	0	0	0
Defecation pain	0	0	0	1 (2)
Defecation difficulties	0	0	0	1 (2)
Wound infection	0	1 (1)	0	0
Inguinal hematoma	0	0	0	0

Data are expressed as number of patients (%).

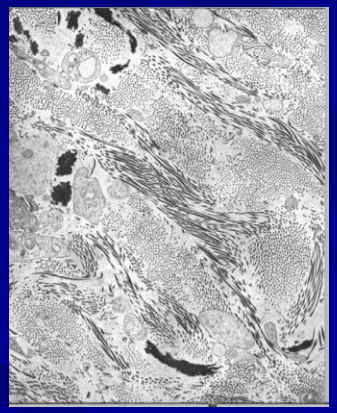
TRENDS IN RECONSTRUCTIVE PELVIC FLOOR SURGERY

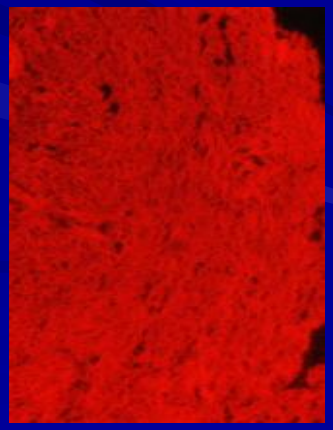


- Future development of pelvic floor reconstruction:



  - Connective tissue
    - metabolic changes
    - Polymorphisms
  - Induction fibroblast formation
  - Tissue engeneering





QUESTIONS TO BE ANSWERED

- Do mesh bending causes postoperative pain and dispareunia?
- How to remove mesh in case of shrinkage, pain or inflamation?
- Which procedure to do in case of recurrence?

Long-term follow-up of laparoscopic sacrocolpopexy

Dimitri Sarlos · LaVonne Kots · Gloria Ryu · Gabriel Schaer

	12 months (n=99)		60 months (n=85)	
	Total number	%	Total number	%
De novo stress incontinence	24	24.2	32	37.6
Surgery for postoperative stress incontinence	15	15.2	16	18.8
Postoperative constipation	1	1.0	4	4.7
Postoperative voiding disorders	8	8.1	11	12.9
De novo urge incontinence	2	2.0	7	8.2
Severe de novo dyspareunia	1	2.1[a]	10	24.4[a]
Quality of life score	9.1		8.3	
Subjective cure rate for prolapse symptoms (in parentheses: number and percentage if every dropout is counted as a failure)	97/99	98.0	81/85 (81/99)	95.3 (81.8)

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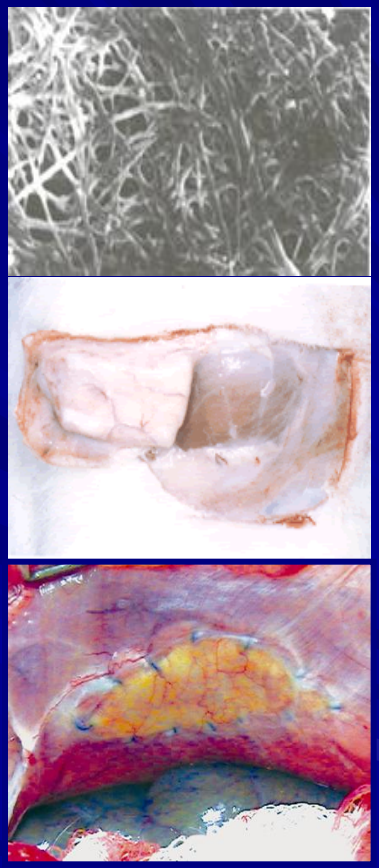
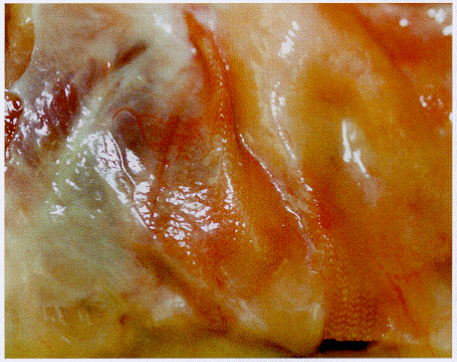
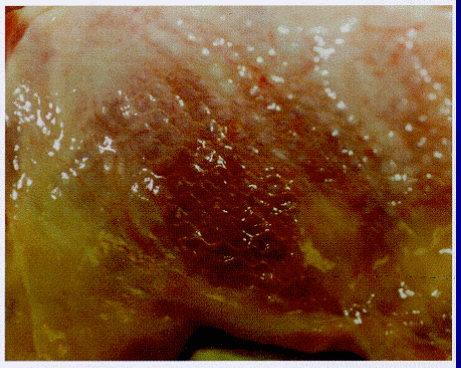
UNANSWERED QUESTIONS AND FUTURE DIRECTION

- Synthetic or biocompatible implants ?
- Evaluation of sexual function
- One incision vs two?
- Other graft materials ?





Heavyweight PP mesh. 90 days post-implantation.
Fold development (implantation study TEP pigs).

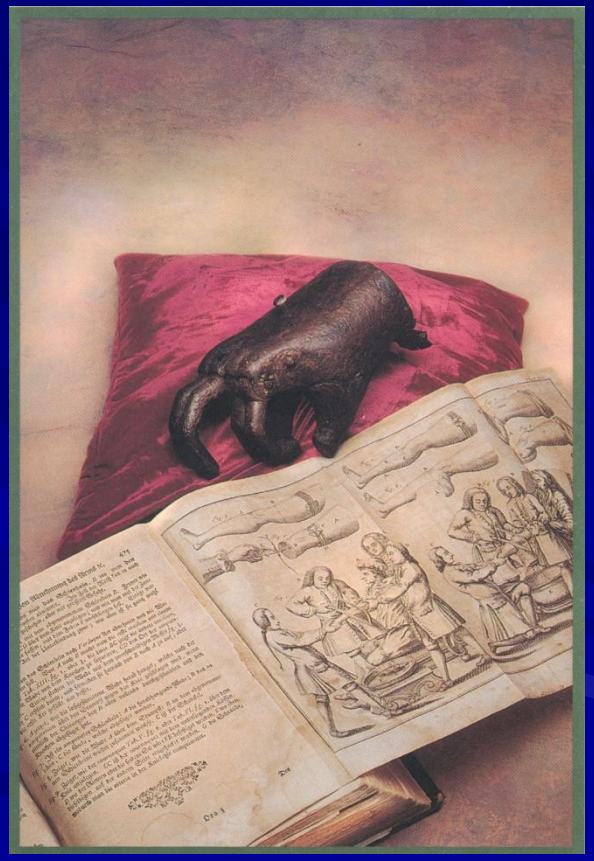


Lightweight VYPRO® II mesh. 90 days post implantation.
Fold-free incorporation (implantation study TEP pigs).

THE RATE OF PELVIC FLOOR RECONSTRUCTIVE SURGERY IS INCREASING

BECAUSE OF:

- Local anaesthesia
- Minimally invasive surgery
- Easier access to urogynecologist
- More attention for life quality
- Increase in life expectancy



FAILURE OF
PEVIC FLOOR RECONSTRUCTIVE SURGERY

- Wrong diagnosis
- Wrong patient selection
- Wrong procedure selected
- Wrong surgical technique
- Wrong post-operative care

POSTOPERATIVE CARE

- Packing
  - 24 hours
- Antibiotics
  - One dose peri-op (Gentamicin 240mg)
  - In certain cases additional doses
- Pain Management
  - Ketoprofen IV
  - Naproksen per os
- Stool softeners
  - Bulking agent plus lubricants (fiber diet)
- Hospital stay
  - 4 (7.4%) patients 2-5 days
  - 50 (92.6 %) patient more then 5 days
- Activity
  - Resume daily “living” activity 72 hours (walking, driving stairs etc.)
  - Avoid abdominal straining (lifting, high impact activity etc.) for 6-8weeks
  - Vaginal rest 6-12 weeks
- Follow up
  - 6 weeks; 6 months - annually for databases

AVOIDANCE OF COMPLICATIONS

- Surgical expertise (learning curve!)
- Meticulous tissue preparation
- Patient positioning-buttocks in safe position (90-100)
- Pre-operative local estrogen treatment
- Absolute asepsis: protection from rectal contamination
- Exact haemostasis
- Antibiotic profilaction

- Many tape related complications may be missed operative injuries
- Tape erosion may occur several years after surgery

Ward & Hilton ICS 2006

THE SURGEON

- Dangerous procedure
- Terrrible complications
- Overuse of surgery / uncritical indications
- Incompetent surgeon / faulty technique

Int Urogynecol J (2009) 20:113–115
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CASE REPORT

Necrotizing fasciitis following transobturator tape treated by extensive surgery and hyperbaric oxygen

Folke Flam · Magnus Boijsen · Folke Lind

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Abstract The transobturator sling procedure (TVT-O) was developed to minimize surgical risks involved in treating genuine stress incontinence. All data suggest that most risks associated with the retropubic route such as injuries to the bladder, intestines or vessels are practically obsolete with the obturator route. However, severe soft-tissue infections have been reported with this new technique. In this case report, necrotizing fasciitis (NF) developed shortly after a TVT-O procedure. This life-threatening complication required extensive debridements, a diverting colostomy, antibiotics, and eight sessions of hyperbaric oxygen (HBO) therapy. We emphasize the importance of a unified interdisciplinary

Introduction

Tension-free vaginal tape (TVT) operations for genuine stress incontinence have been performed for 15 years with only a few published reports of necrotizing fasciitis (NF), a potentially devastating condition. We have found 17 published cases of NF associated with obturator sling procedures during either TOT (outside-in technique) or TVT-O (inside-out technique). Most of these are listed in a recent report [1]. Uncharacteristically, the majority became sick at least 6 months following the procedure and invariably there was an erosion visible in the vaginal wall.

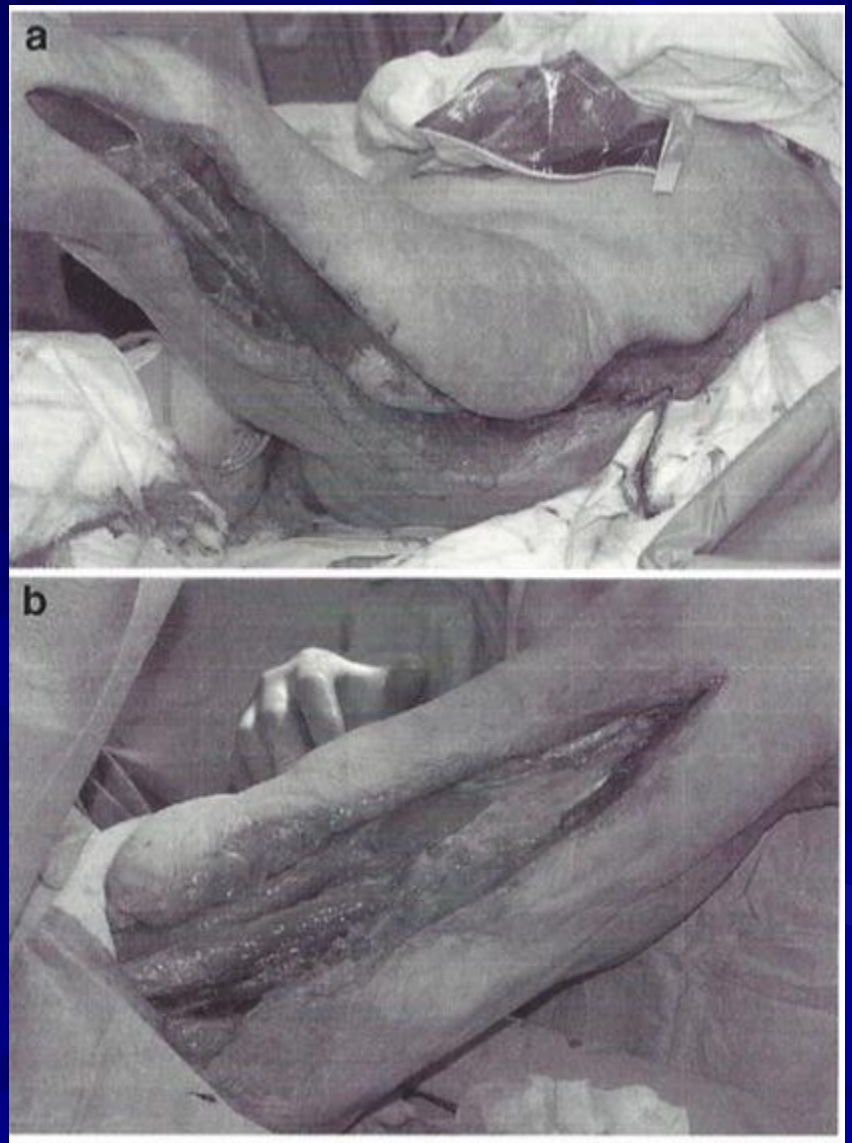


Fig. 1 Lateral (**a**) and medial (**b**) incisions in left leg and flank after 1 week of surgery and HBO immediately before secondary suture

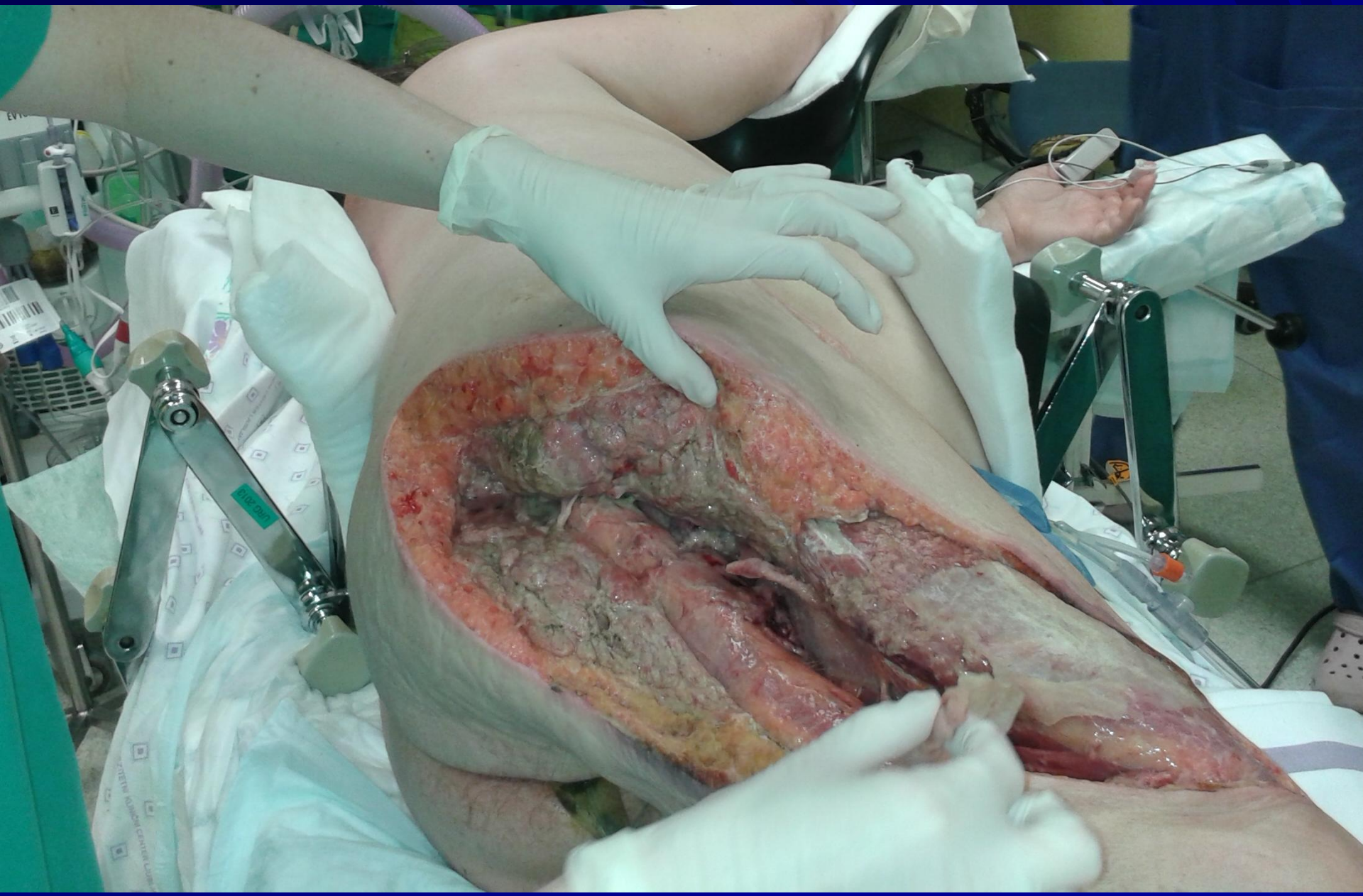
CASE REPORT

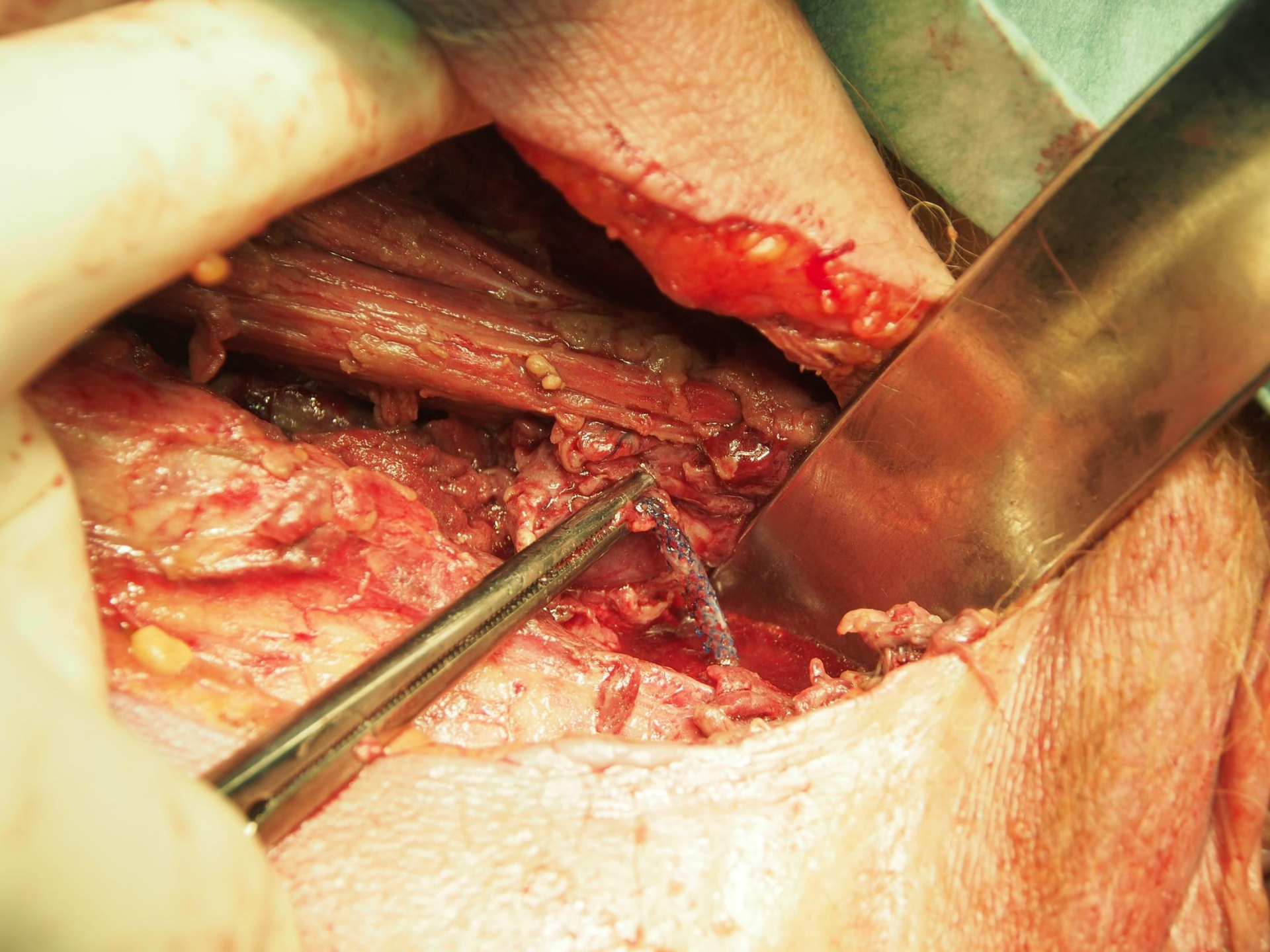
Dg: *Fascitis necrotisans glutei et extremitatis inferioris lat.dex.*

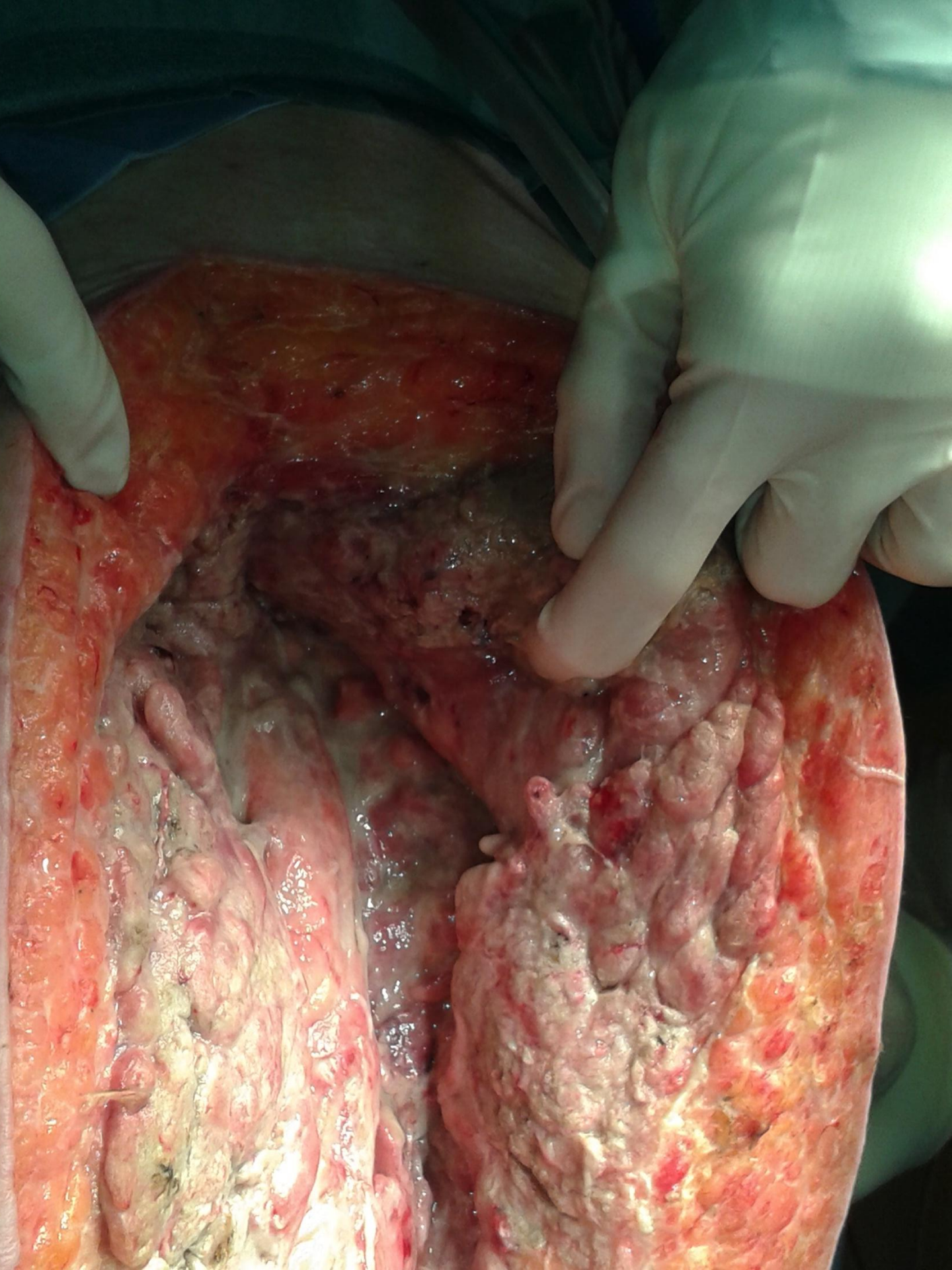
Patient: KD, born 1954

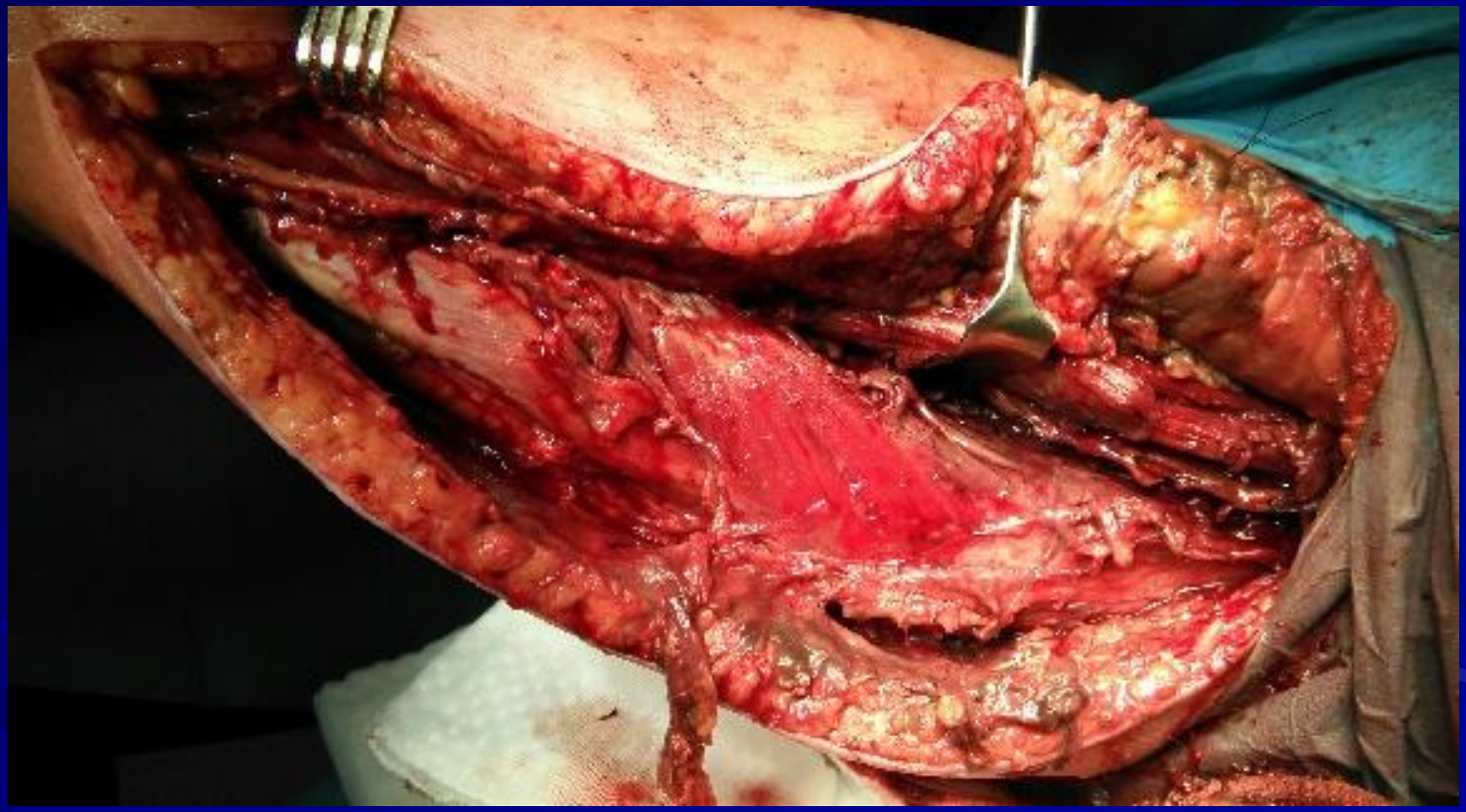
OP: *TVT-O* (Gynecare) 5.5.2009, released 1st postoperative day, routine operation

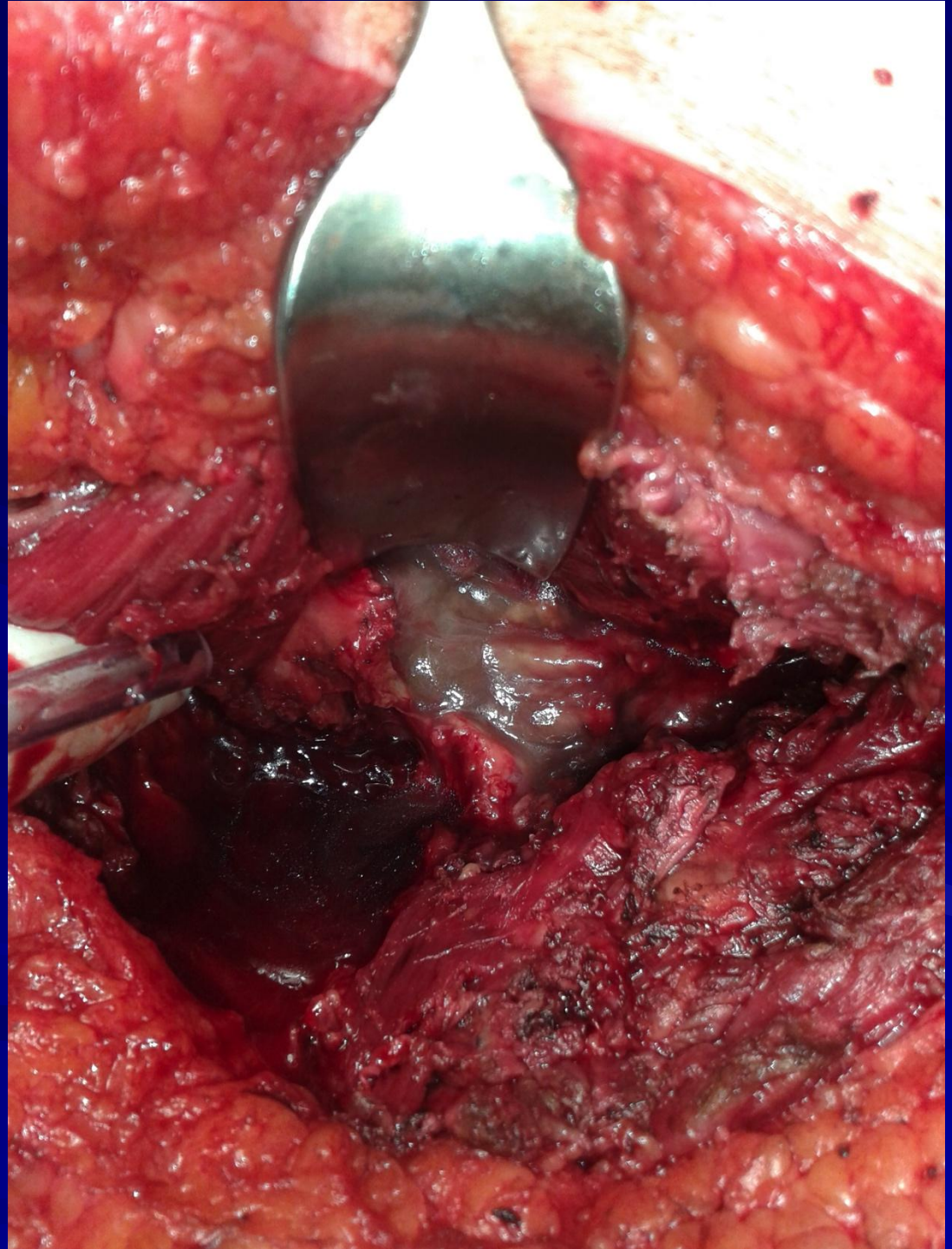
Admited to the Dpt of Infectious disesases on 5th of January 2015 because of…

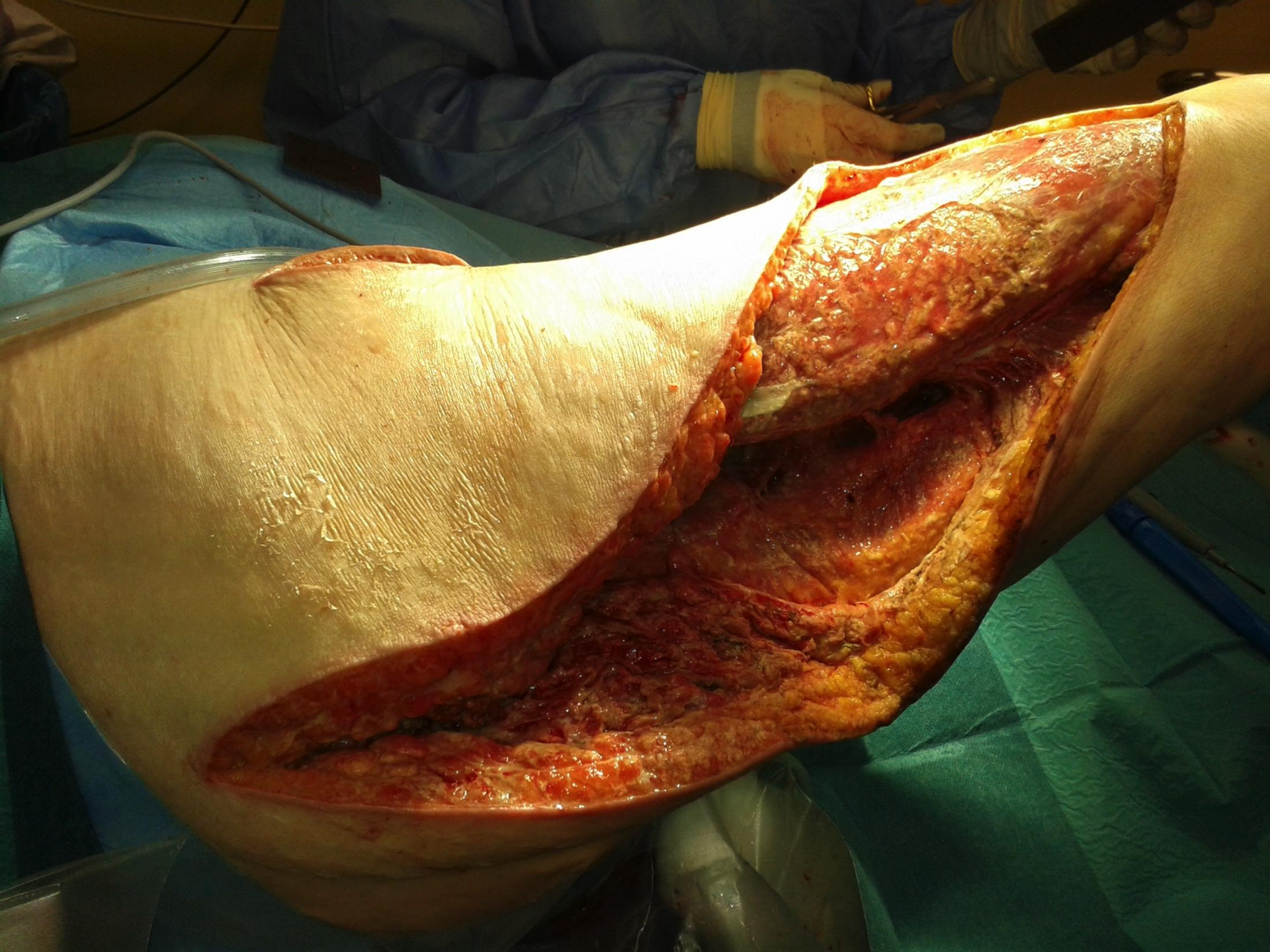












VAC - VACUUM-ASSISTED CLOSURE

It is used to remove blood or serous fluid from a wound or operation site.

1. a piece of foam with an open-cell structure is inserted into the wound
2. a wound drain with lateral perforations is laid atop it
3. the entire area is then covered with a transparent adhesive membrane, which is firmly secured to the healthy skin around the wound margin
4. When the exposed end of the drain tube is connected to a vacuum source, fluid is drawn from the wound through the foam into a reservoir for subsequent disposal.


ERBE
ICC 350
ERBE

CONCLUSIONS

- Training essential
- Failure – method, patient or doctor
- RCT - evidence essential
- Prospective comparative studies necessary
- National audit for each technique
  - continence outcome data
  - complications (as in USA)

- Great advances in recent decades
- Still tremendous amounts to learn
- We must agree on definitions of success
- We must collaborate

We have come a long way-we have only just begun

Harold P. Drutz Founding member of IUGA