

The Ins and Outs of Pelvic Organ Prolapse



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1

Presentation Overview

- Epidemiology of prolapse
- Female pelvic anatomy
- Etiology of prolapse
- Management of prolapse
- Grafts in pelvic surgery

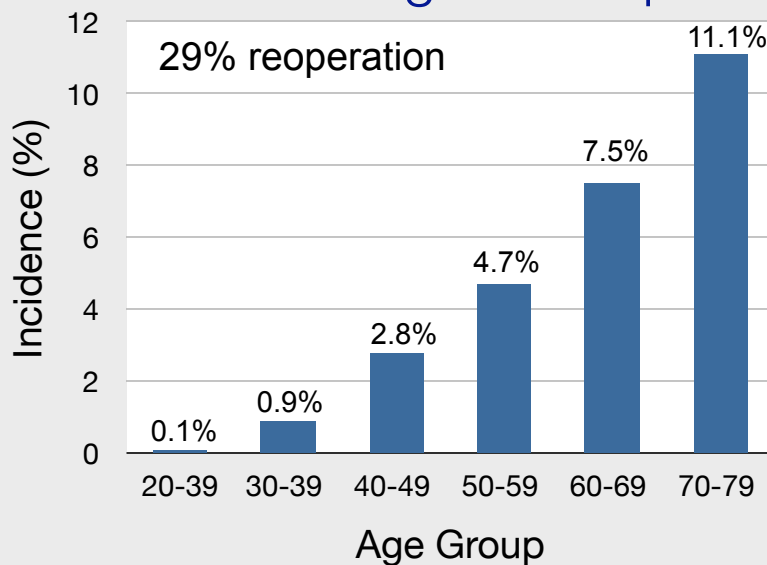
2

POP

- Prolapse likened to a hernia of pelvic contents through genital hiatus
- Significant QOL issues
 - Physical discomfort
 - Effect on urinary, bowel and sexual function
 - Body image

3

Surgery for Urinary Incontinence or Pelvic Organ Prolapse



Olsen et al. Obstet Gynecol 1997;89(4):501-506

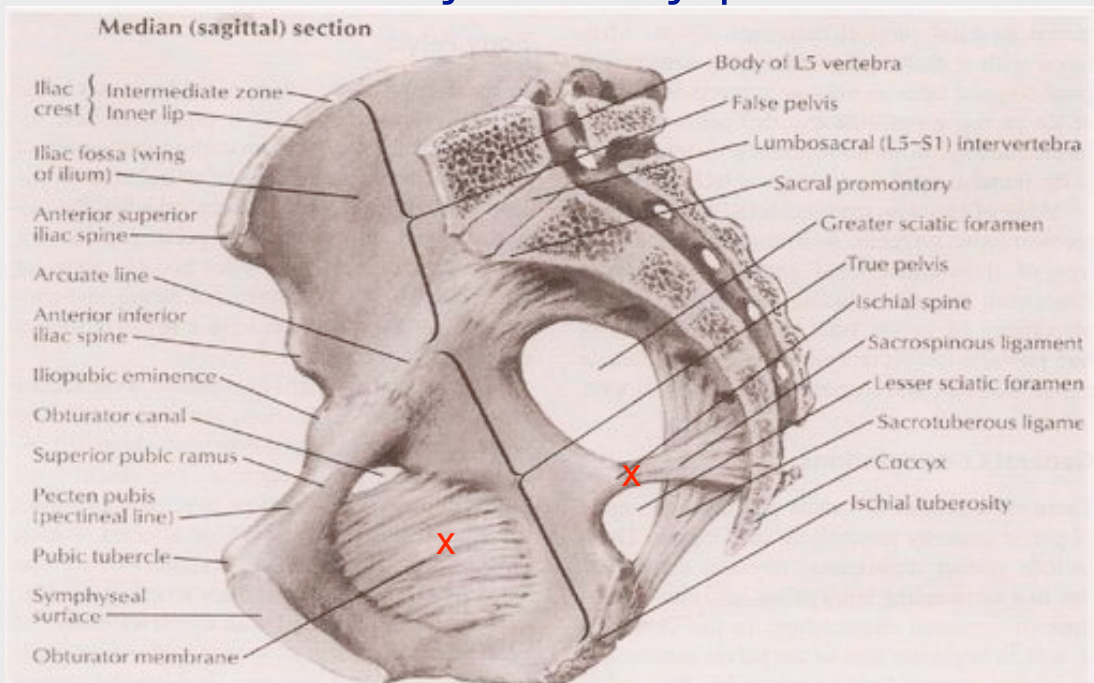
4

Anatomy

- Bony pelvis
- Pelvic diaphragm
- Endopelvic fascia

5

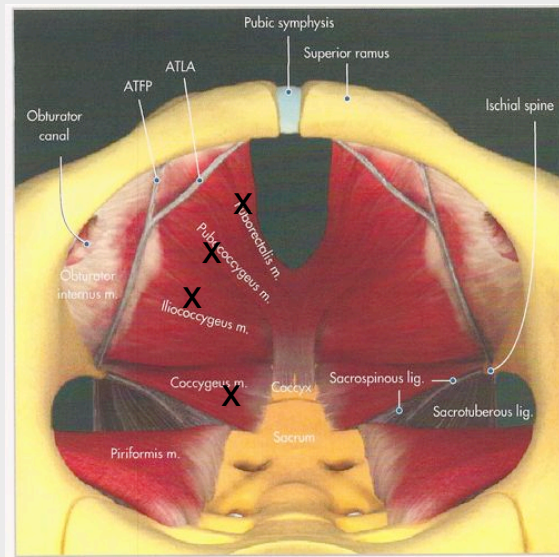
Anatomy - Bony pelvis



6

Anatomy

- Pelvic diaphragm
 - Levator Ani : puborectalis, pubococcygeus, ileococcygeus
 - Coccygeus muscle

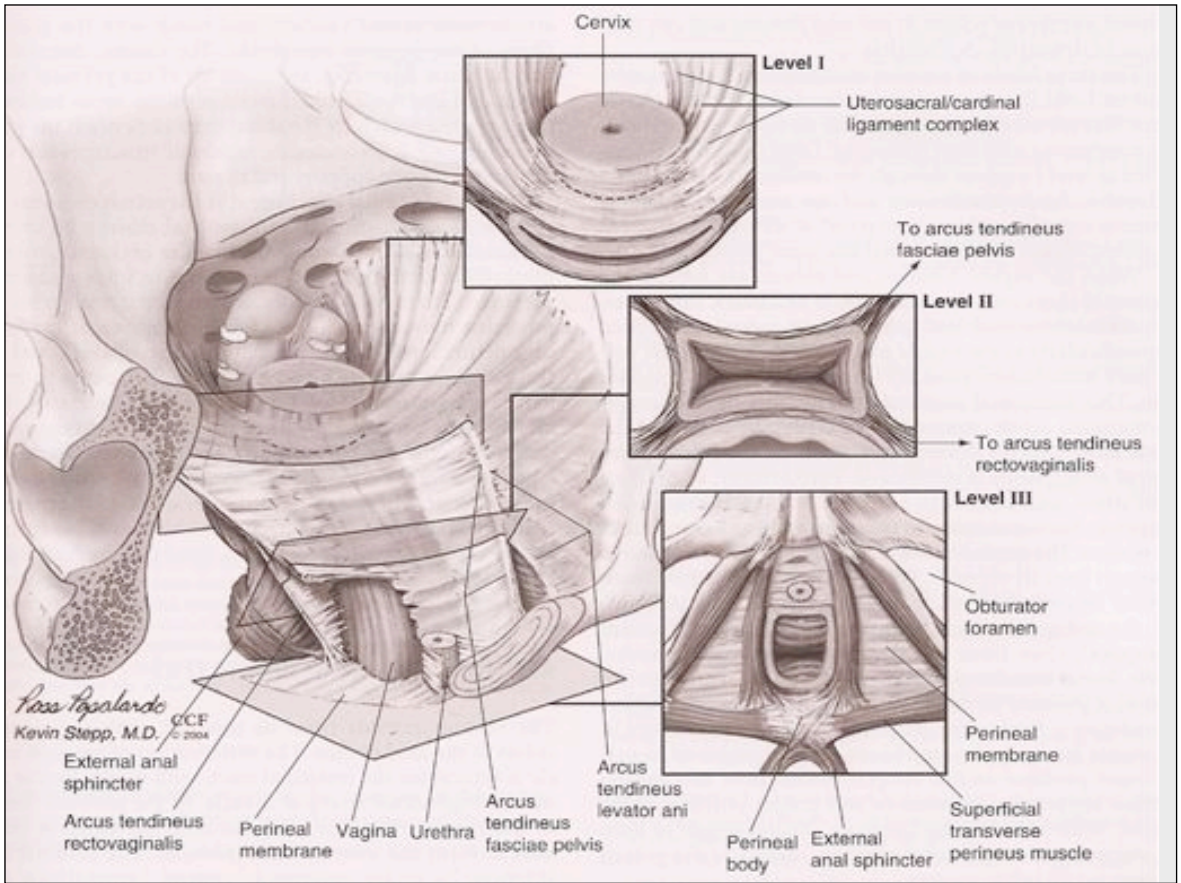


7

Anatomy

- Endopelvic fascia
 - Continuous sheet of connective tissue
 - Fibromuscular layer
 - Supports pelvic viscera and pelvic muscles
 - Ligaments are condensations of CT

8



9

Etiology of prolapse

10

Etiology of POP

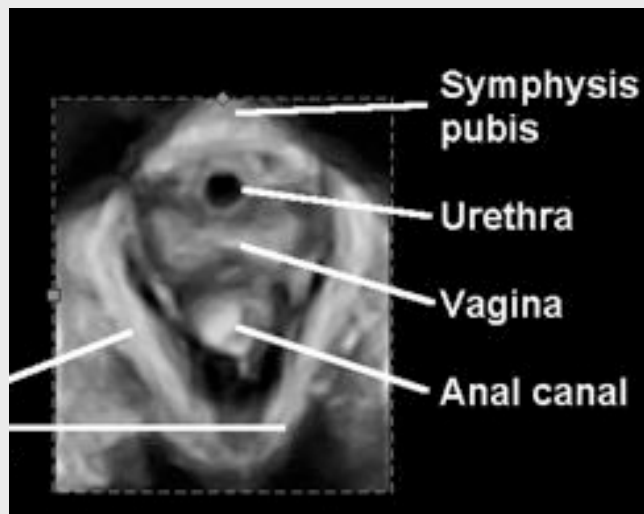
- Normal form maintained by action of pelvic diaphragm and endopelvic fascia
- Pelvic diaphragm
 - Resting tone
 - Active contraction during raised intra-abdominal pressure
- Endopelvic fascia
 - Provides support to viscera during relaxation of pelvic diaphragm

11

Etiology of POP

- Disruption of fascia and/or pelvic diaphragm results in POP
 - Stretching/tearing of fascia
 - Neuropathic injury - pudendal nerve
 - Disruption of muscle attachment

12



13

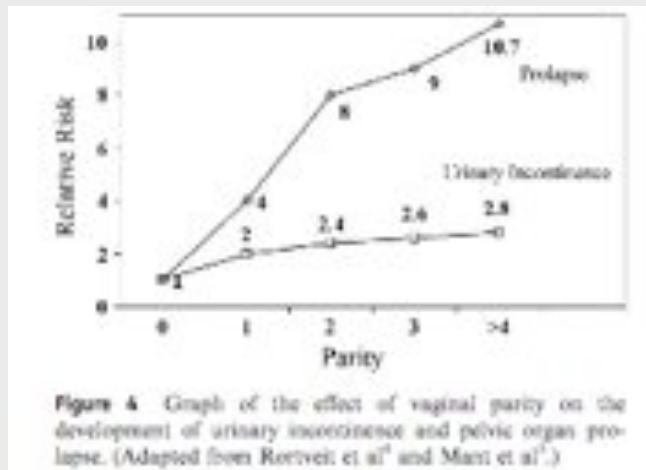
13

Etiology of POP

- Risk factors
 - Age : effect on connective tissue and muscle function
 - Vaginal parity : tearing/detachment of CT and levator ani, neuropathy
 - Menopause : role of estrogen unclear
 - Previous pelvic surgery : hysterectomy
 - Race
 - Chronic increased intra-abdominal pressure : COPD, constipation, obesity
 - Lifestyle : high-impact activities

14

Etiology of POP - Parity



15

Management of POP

- Prolapse presents with wide range of clinical findings
- Management guided by patient symptoms



Management of Prolapse

Conservative

Observation

Asymptomatic
Progression 11%
Regression 2% ⁽¹⁾

Pessary



⁽¹⁾Bradley CS et al. Obstet Gynecol. 2007 Apr;109(4):848-54.

Pessary



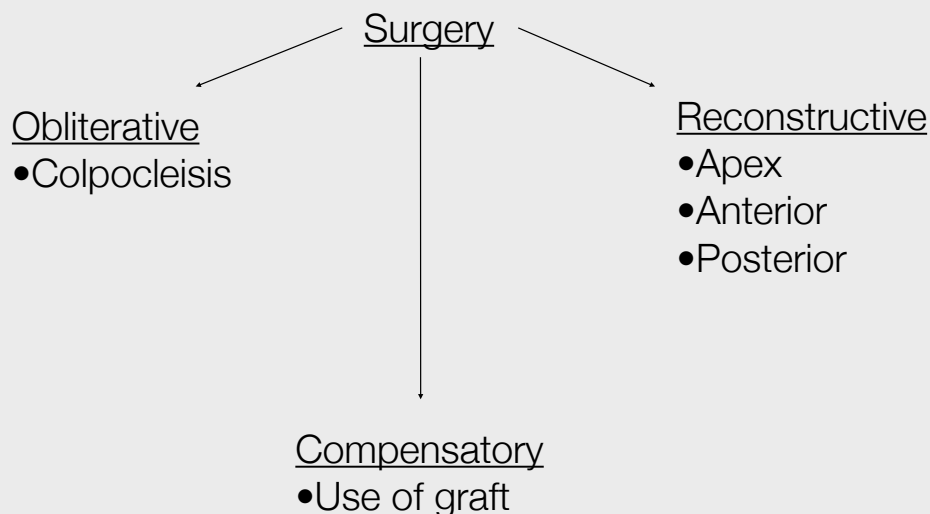
PESSRI Study

Management of POP Surgery

- Choice of procedure
 - Patient characteristics: age, suitability for surgery, primary or recurrent prolapse, site of prolapse, risk for recurrence
 - Surgeon experience and preference

19

Management of Prolapse



20

Reconstructive Surgery



Sacrocolpopexy

Open⁽¹⁾

78-100% (apex)

58-100% (any)

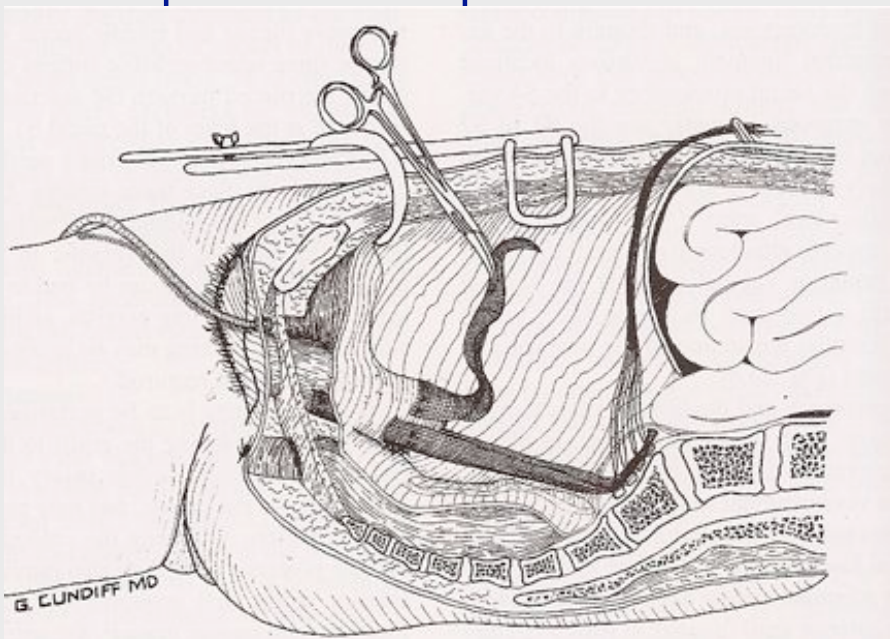
Laparoscopic⁽²⁾

94%

(1) Nygaard et al. Obstet Gynecol 2004;103:805-23

(2) Ganatra AM, et al., Eur Urol 2009. Epub Feb 4

Reconstructive Surgery Apical compartment



Reconstructive Surgery



Sacrocolpopexy

Open

78-100%(apex)

58-100%

(any)

Laparoscopic

93-98%

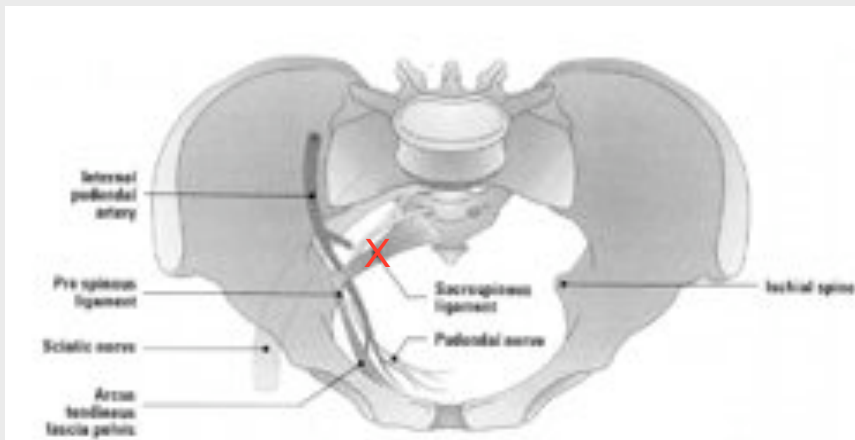
Sacrospinous ligament suspension

63-97%

Nichols et al. J Pelvis Surg 1996;2:87-94
Lantzsch et al. Arch Gynecol Obstet 2001;265:21-25
Benson et al. Am J Obstet Gynecol 1996;175:1418-1422
Paraiso et al. Am J Obstet Gynecol 1996;175:1423-1430

23

Reconstructive Surgery Apical compartment



24

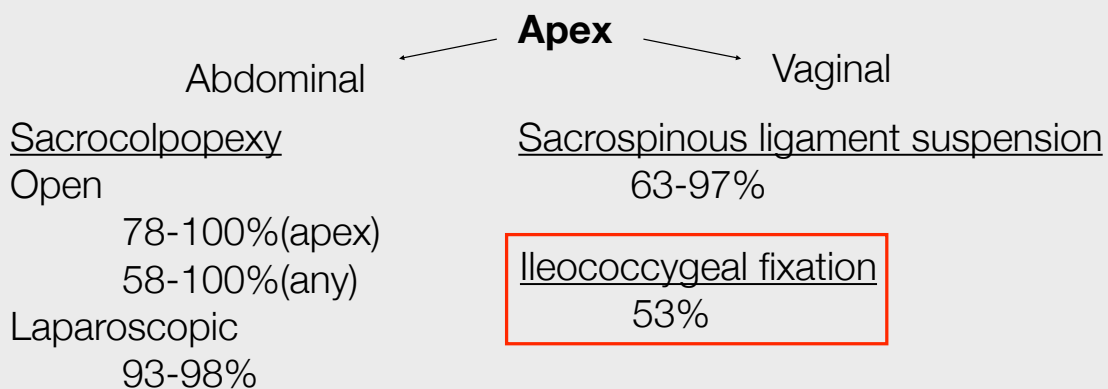
Reconstructive Surgery

Apical compartment

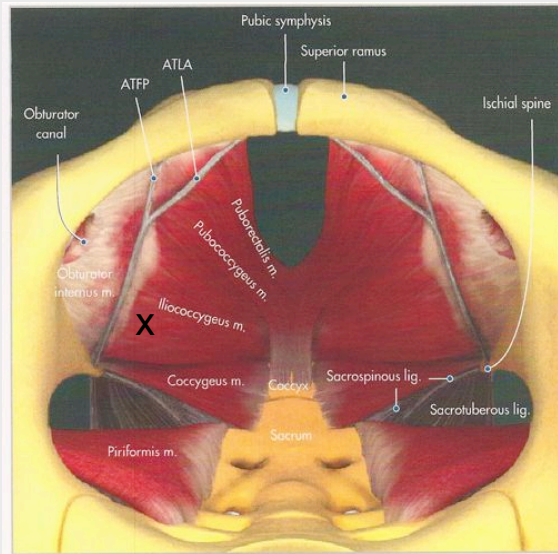


25

Reconstructive Surgery

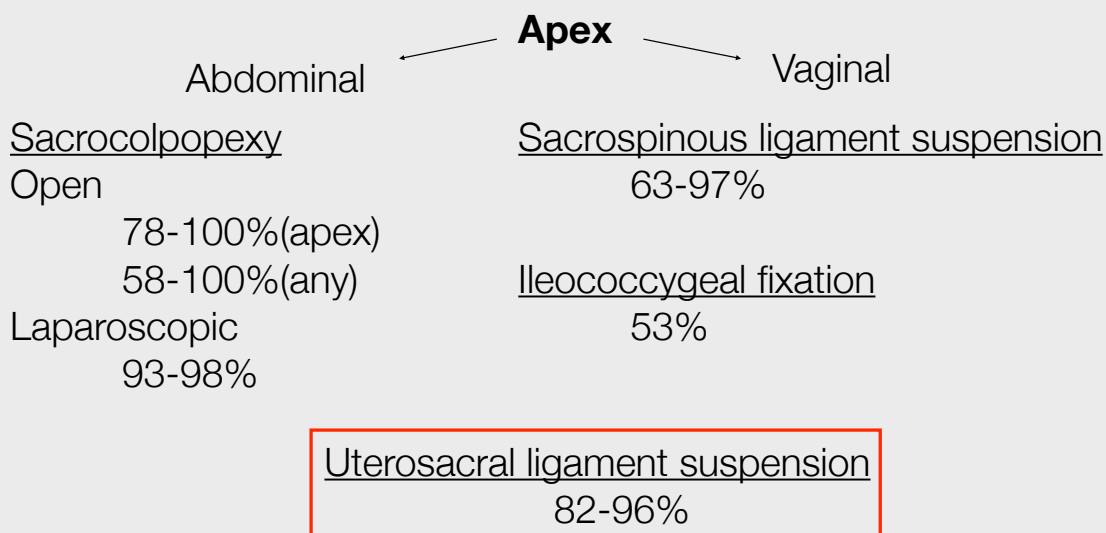


Reconstruve Surgery Apical compartment



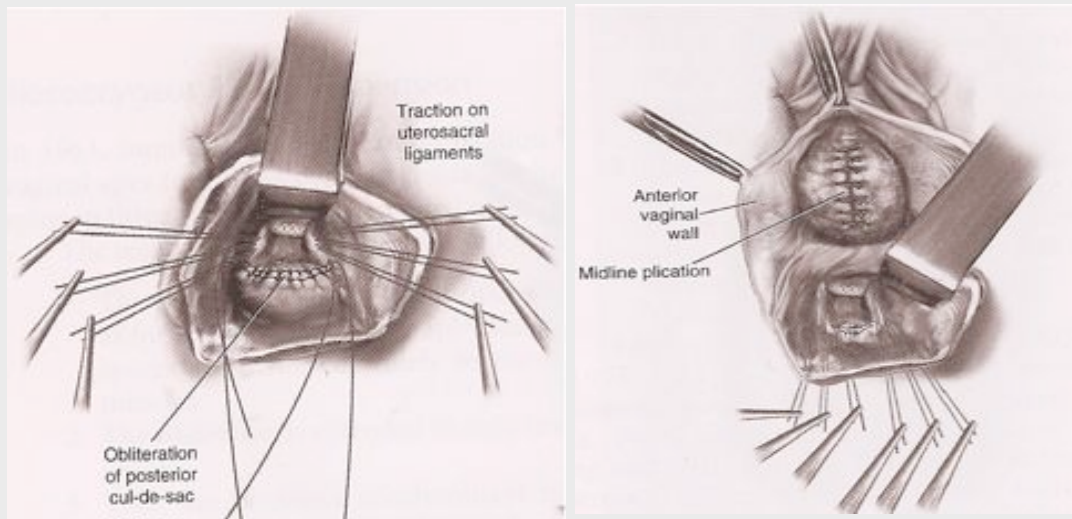
27

Reconstructive Surgery



Reconstructive Surgery

Apical compartment



29

Reconstructive Surgery

Anterior

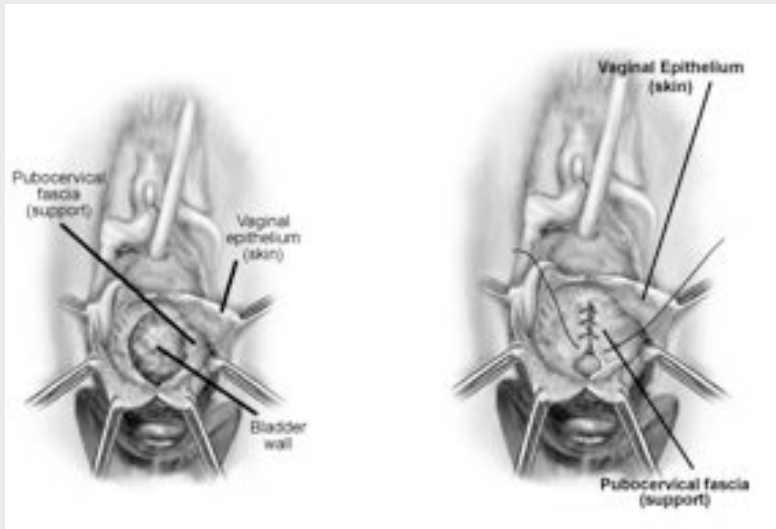
Traditional colporrhaphy
37-57%

Posterior

Traditional colporrhaphy
76-96%

30

Reconstructive Surgery



31

Reconstructive Surgery

Anterior

Traditional colporrhaphy
37-57%

Site-specific repair
75-97%

Posterior

Traditional colporrhaphy
76-96%

Site-specific repair
56-100%

32

Procedure	Level I	Level II	Level III
Sacrocolpopexy	+		
Sacrospinous fixation	+		
USL fixation			+
Iliococcygeal fixation			+
Colporrhaphy	+		
Site specific repair			+

Grafts

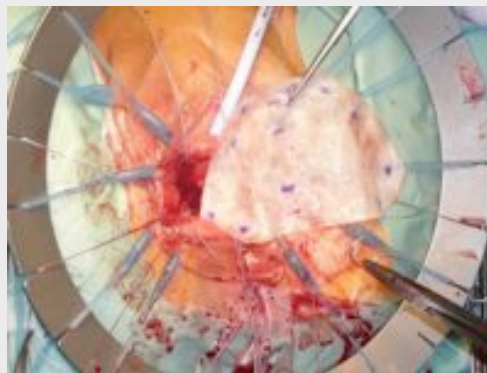
Grafts in Pelvic Surgery

- Introduced in an effort to address the high reoperation rate of prolapse surgery
- Graft provides reinforcement of fascial repair by acting as a scaffold for tissue ingrowth

35

Grafts in Pelvic Surgery

- Graft cut to size & shape required
- Placed or sutured
- May be combined with apical support procedure



36

Grafts in Pelvic Surgery

- “Ideal” Graft
 - High efficacy
 - Low cost
 - Low complication rate
 - Doesn't exist!
- Biologic vs Synthetic grafts
 - Autologous vs Absorbable
 - Allograft vs Non-absorbable
 - Xenograft

37

Grafts in Pelvic Surgery- Biologic

- **Autologous** - fascia lata, rectus sheath
 - Pros:
 - No risk of communicable disease
 - No erosion
 - Incorporated without disintegration
 - Cons:
 - Separate incision, increased operating time
 - Inconsistent quantity and quality
 - Pain at donor site
 - Herniation at donor site

38

Grafts in Pelvic Surgery- Biologic

- **Allograft** - cadaveric fascia lata, dura, dermis
- **Xenograft** - porcine dermis/small intestine, bovine pericardium
- Pros:
 - Low erosion risk
- Cons:
 - Potential for prion/viral infection; rejection
 - Expensive (\$200 - \$1200)
 - Availability(cadaveric)
 - Limited durability: processing may weaken material

39

Grafts in Pelvic Surgery- Synthetic

- Absorbable (Vicryl, Dexon) vs
- Non-absorbable (Prolene, Gore-tex, Teflon) vs
- Combined (Vypro)
- Pros:
 - Cost-effective cf. allo- & xenograft
 - Consistent material and availability
 - No disease transmission
- Cons:
 - Infection
 - Erosion: vagina, urethra/bladder, bowel

40

Synthetic Non-absorbable Mesh

- Synthetic mesh classified according to:
 - pore size: macro (>75 microns) vs microporous (<10 microns)
 - weave: mono vs multifilament
- Pore size important in determining host inflammatory response and tissue incorporation

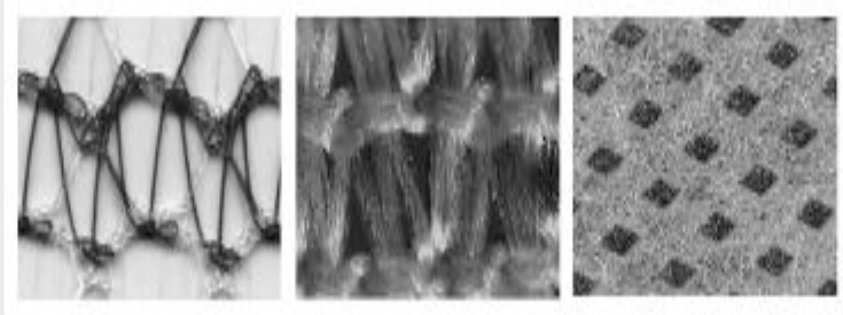
41

Synthetic Non-absorbable Mesh Classification

- Type I - macroporous, monofilament
 - Prolene, Marlex
- Type II - microporous(<10 microns), mono & multifilament
 - Gore-tex
- Type III - macroporous, multifilament
 - Mersilene, OBtape, IVS tunneler
- Type IV - submicronic pores, not used in pelvic surgery

42

Synthetic Non-absorbable Mesh Classification



Type I

Large pores

Monofilament

Type II

Small pores

Multifilament

Type III

Large pores

Multifilament

43

Evidence for grafts in pelvic surgery

- “Evidence” difficult to determine
 - Varying quality of study design
 - Majority are retrospective
 - Definition of outcomes varies - objective, subjective
 - Follow-up periods vary
 - Different materials used
 - Different techniques
 - Graft shape
 - Placement

44

Evidence for grafts in pelvic surgery

- Sacrocolpopexy
 - “Gold standard” for apical prolapse repair
 - 8 RCT’s
 - Prolene most studied graft

Maier C 2007. Surgical Management of Pelvic Organ Prolapse in Women (Review). Cochrane Collaboration

45

Evidence for grafts in pelvic surgery

- Vaginal prolapse repair
- Systematic review & meta-analysis
 - 49 studies - RCT (6 full, 11 abstracts), 7 non-randomised comparative studies, 1 prospective registry, 24 case series (>50 women)
 - Comparator either no mesh or different mesh
 - 50% used non-absorbable synthetic mesh

Jia et al. BJOG 2008;115:1350-61

46

Evidence for grafts in pelvic surgery

- Anterior wall repair
 - 10 RCT's, 1148 women
 - Mesh/graft (any type) better than no mesh
 - RR 0.48 (95% CI 0.32-0.72)
 - Improved results with non-absorbable synthetic mesh (RR 0.24 CI 0.13-0.43) cf biological graft (RR 0.55 CI 0.37-0.81) and absorbable synthetic (RR 0.74 CI 0.46-1.18)

47

Evidence for grafts in pelvic surgery

- Posterior vaginal repair
 - Role for mesh less clear as native tissue repair yields 76-90% success rates
 - 9 studies (3 RCT's), 417 women
 - Trend in crude rates for better outcomes with non-absorbable mesh cf absorbable mesh/biologic graft and no mesh - too few data for statistical analysis

48

Evidence for grafts in pelvic surgery- Posterior

Author	N	F/U	Outcome
Sand 01	PC 70	12m	90%
	Vicryl 73		92%
Paraiso 06	PC 37	17m	86%
	SSR 37		78%
	Porcine SIS 32		54%
Lim 06 (AUGS abstract)	SSR 31	12m	No significant difference in anatomical outcomes
	Vypro2 25		
	Vicryl 9		

49

Mesh kits

- FDA - does not require pre-market approval for medical devices
- Pre-market notification of proposed device only requires demonstration of “substantial equivalence” to another legally US marketed device

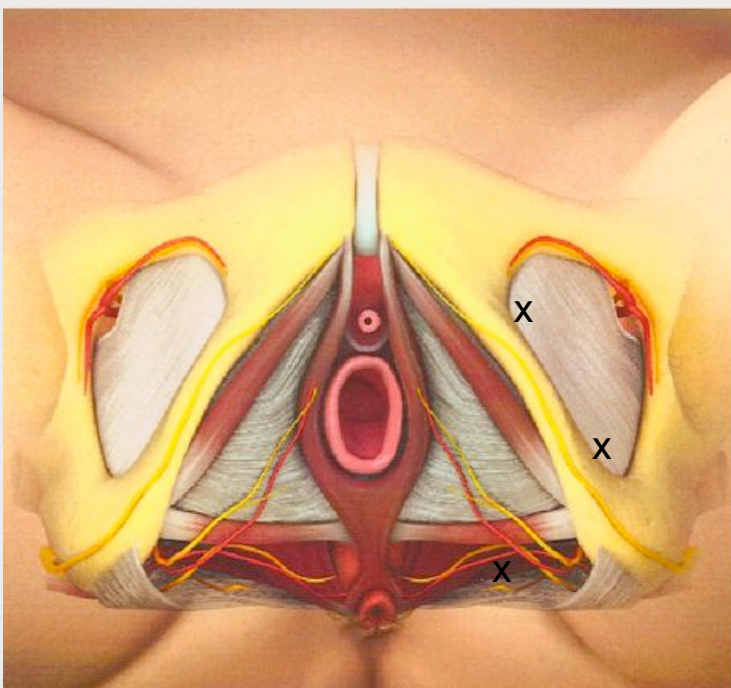
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Mesh kits

- Introduced 2001
- Gynecare (Johnson & Johnson):
 - Prolift
- American Medical Systems:
 - Perigee
 - Apogee
- Bard
 - Avaulta

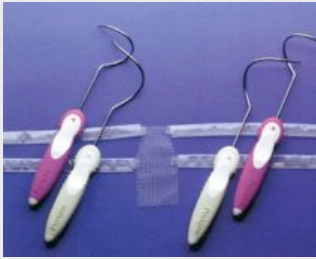
51

Mesh Kits - Anatomy



52

Mesh Kits

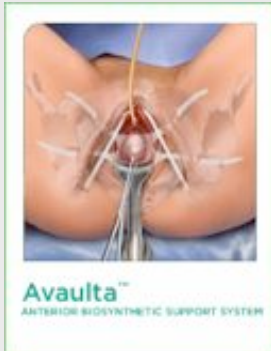


Perigee

Apogee



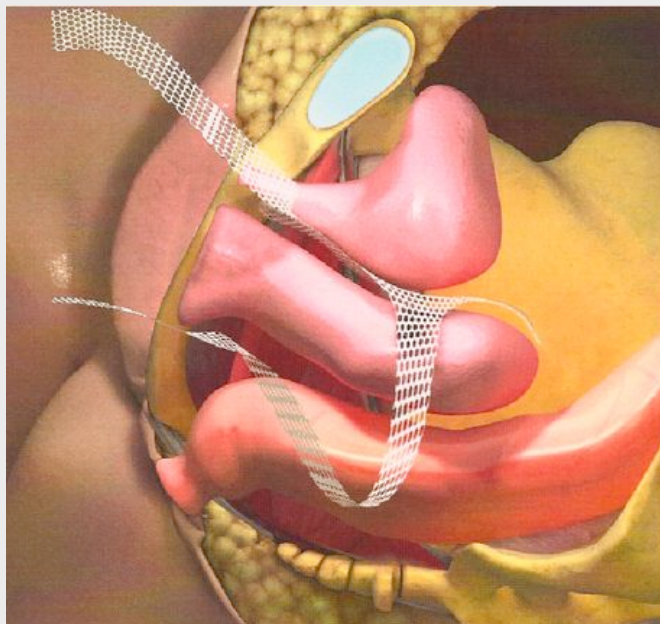
Prolift



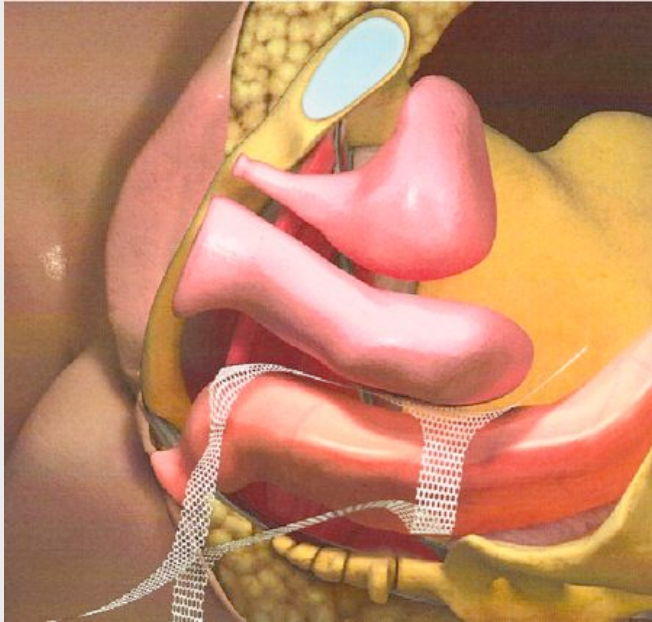
Avaulta Anterior and Posterior



Mesh Kits

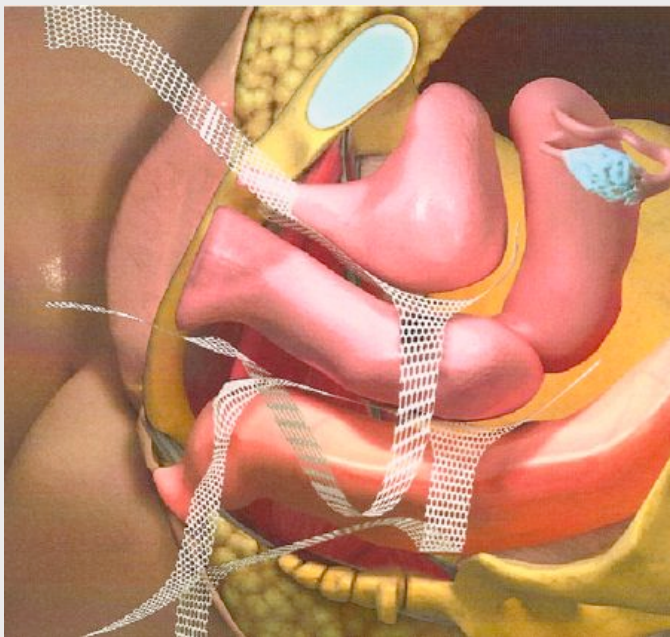


Mesh Kits



55

Mesh Kits



56

Mesh Kits - Literature Level III Evidence

Author	Device	N	F/U	Anatomical cure	Mesh erosion
Cosson 05	Prolift	687	3m	94%	6.7%
Garunder-Burmester 07	Perigee Apogee	120	12m	93%	11%
Altman 07	Prolift	123	2m	Anterior 87% Posterior 91% Combined 88%	-
Abdel-Fatah 08	Prolift (76%) Perigee/Apogee (24%)	289	3m	94-100%	10%
Van Raalte 08	Prolift	97	19m	Overall 86% Apex 96%	0%
Balakrishnan 08	Apogee	35	6m	97%	25%
Elmer 09	Prolift	232	12m	Anterior 79% Posterior 82%	11%

57

Mesh Complications - Erosion

- Sacrocolpopexy
 - Median erosion rates 3.4% (Prolene 0.5%, Teflon 5.5%) ⁽¹⁾
 - Risk factors for erosion⁽²⁾
 - Current smoking OR 5.2
 - Concurrent hysterectomy OR 4.9
 - Gore-tex mesh OR 4.2

⁽¹⁾ Nygaard et al. Obstet Gynecol 2004;103:805-23

⁽²⁾ Cundiff et al. AmJOG 2008;199:688.e1-e5

58

Mesh Complications - Erosion

- Transvaginal mesh
 - Paucity of quality data
 - Mesh erosion greater with synthetic non-absorbable mesh (10%) cf biological graft (6%) and synthetic absorbable mesh (0.7%)



Jia et al. BJOG 2008;115:1350-61

59

FDA - Center for Devices and Radiological Health

- FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
- Issued: October 20, 2008

60

FDA - Center for Devices and Radiological Health

- Obtain **specialized training** for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially **erosion and infection**.
- Watch for **complications** associated with the **tools** used in transvaginal placement, especially **bowel, bladder and blood vessel perforations**.

61

FDA - Center for Devices and Radiological Health

- Inform patients that implantation of **surgical mesh is permanent**, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for **serious complications** and their **effect on quality of life**, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a **written copy of the patient labeling** from the surgical mesh manufacturer, if available.

62

SGS Guidelines for Use of Vaginal Graft

- Anterior compartment
 - *Non-absorbable synthetic mesh may improve anatomical outcomes of anterior vaginal wall repair, but there are significant trade-offs in regard to the risk of adverse events*

Murphy M. Obstet Gynecol 2008;112(5):1123-1130

63

SGS Guidelines for Use of Vaginal Graft

- Posterior compartment
 - *It is suggested that native tissue repair remains appropriate in posterior vaginal wall repair when compared with biologic and absorbable synthetic graft*
 - *There are no comparative studies to guide any recommendation for the use of non-absorbable synthetic mesh in posterior vaginal wall repair when compared with native tissue repair*

64

SGS Guidelines for Use of Vaginal Graft

- Multiple compartment
 - *There are no comparative studies to guide any recommendation for the use of biologic, absorbable synthetic or non-absorbable synthetic mesh in multiple compartment repair when compared with native tissue repair*

65

SGS Guidelines for Use of Vaginal Graft

- Need adequately powered randomized comparative studies
 - Outcomes assessments using validated, standardized tools
 - Subjective (function) AND objective cure (form)
 - Follow-up at least 1 year, ideally 5+ years
 - Complications

66

Pre-operative Patient Counseling when using Graft

- Unknown durability
- Risk of erosion
- Lack of long-term data on adverse events
 - Chronic pain
 - Dyspareunia
 - Fistula
 - Infection
 - Delayed erosion/exposure

67

Summary

- Pelvic organ prolapse is a complex problem
- Lack of high quality evidence to guide surgical management
- Use of graft in pelvic surgery is under evaluation, currently no strong evidence to guide it's use

68

Summary

- Use of graft
 - Sacrocolpopexy
 - Recurrent prolapse
 - High risk for recurrence
- Full disclosure of risks to patient

69

THANKYOU



70