Use of Biological Materials in Female Pelvic Floor Reconstruction. What's new?

W25, 16 October 2012 09:00 - 10:30

Start	End	Topic	Speakers
09:00	09:20	Biochemical evidence in tissue repair	• Ajay Singla
09:20	09:40	What does research say about biological materials	• Dirk de Ridder
09:40	10:00	Clinical evidence in use of biological materials	• Rahmi Onur
10:00	10:20	Mesh complications	• Paulo Palma
10:20	10:30	Discussion	All

Aims of course/workshop

The aim of this workshop is to familiarise the audience regarding various biological materials which are in use in female pelvic floor reconstruction. What are the complications observed and FDA warning.

Educational Objectives

This has a great educational value for people who are using these products which are made available by the industry. We should be careful regarding their problems.

"Bio"-meshes

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Our laboratory has been supported by unconditional grants from Bard, Cook, Tyco, Ethicon, AMS

Implants

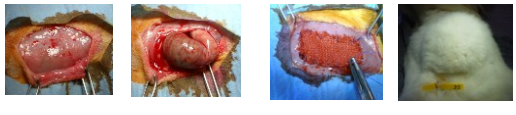
Xenografts
End 1990s
FDA approved for urogynaecology
CE marked


Non-cross linked
Small intestinal submucosa « SIS »
InteXen (LP)

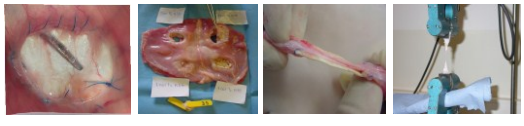
Cross linked
Pelvicol
Pelvisoft

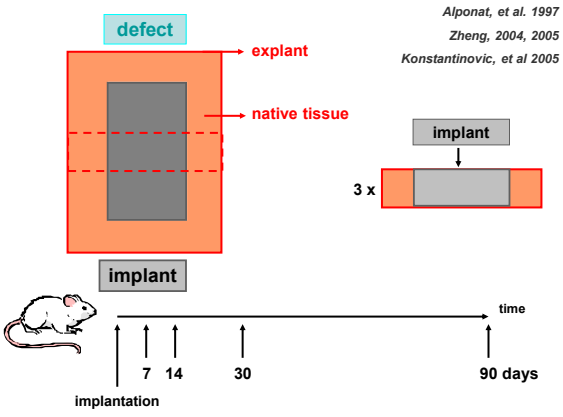

different host response, local side effects and durability ?

In vivo animal studies



Rat (3-90 d) and rabbit model (30d-2 yrs)

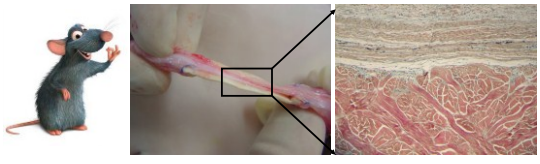




Alponat, et al. 1997
Zheng, 2004, 2005
Konstantinovic, et al 2005

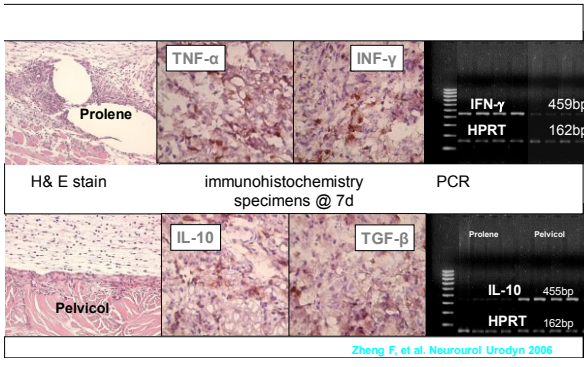
Xenografts – experimental data

Host response to acellular collagen matrix



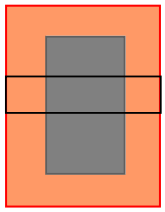
Weak inflammatory response
Less pro-inflammatory profile
Poor integration
Poor vascularization and collagen deposition

polypropylene provokes "pro-inflammatory" response = rejection
xenografts induce anti-inflammatory cytokines = "tolerance"

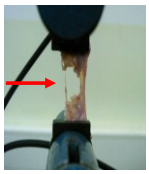


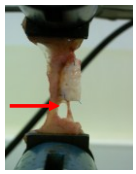
Zheng F, et al. Neurourol Urodyn 2006

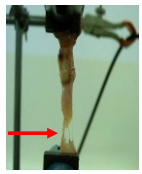
Tensiometry of explant (in vivo)



4467 Instron tensiometer
Specimen: 1 x 5 cm
Crosshead speed: 2 cm/ min
Measurement:
maximum load to disrupt (N)
Location of disruption:
in mesh
or at interface





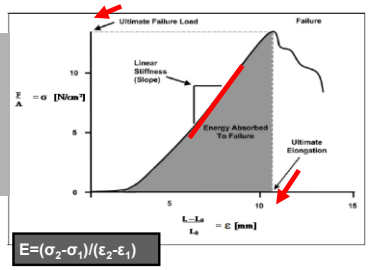


Uni-directional stress/strain plot

elastic area
E is measure of slope

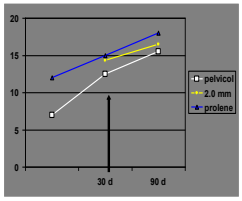
plastic area
permanent deformation

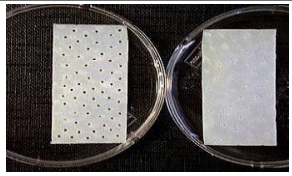
Main purpose: failure level
Determination of
Stress
Strain
Stiffness

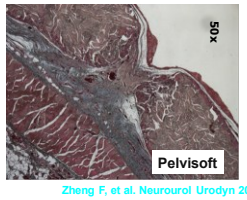


$E=(\sigma_2-\sigma_1)/(\varepsilon_2-\varepsilon_1)$

Cross linked products



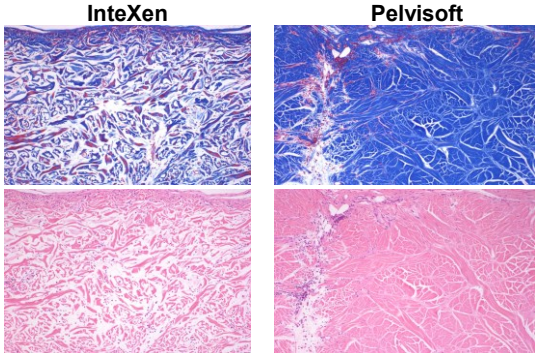




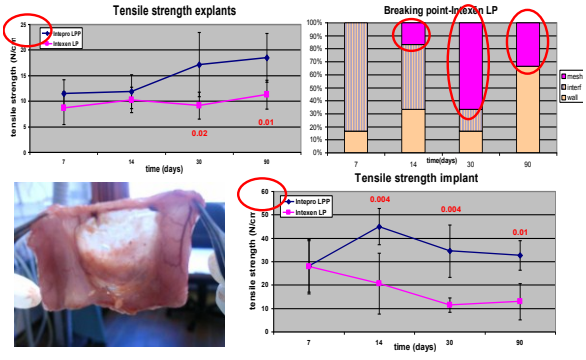
Zheng F, et al. Neurourol Urodyn 2005

Structure of implant

InteXen | Pelvisoft

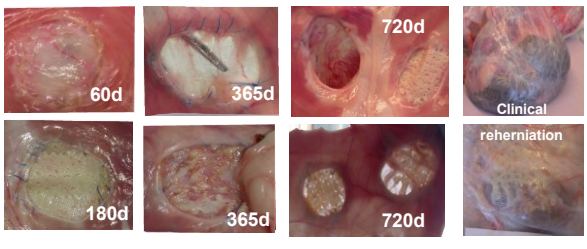


Non-cross linked products

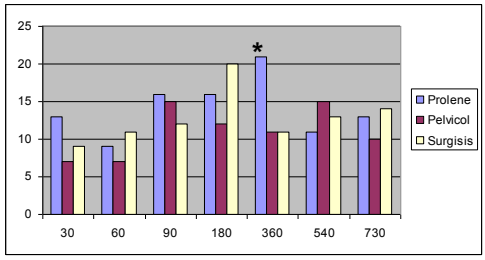


Ozog and Konstantinovic – 2006-2008

Experimental long term studies



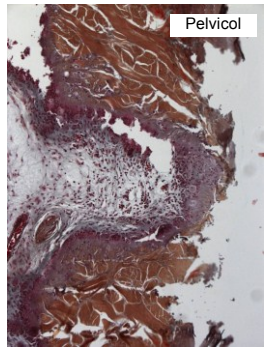
Rabbits - explant strength



- Overall comparable performance
- reherniations in both bio-groups
- 25 % of SIS implants tear at the implant
- Loss of elasticity

Claerhout et al, 2004, AJOG 2008
Trabuco et al, AJOG 2008

long term inflammatory changes



Conclusions - 1

Xenografts “ideal template” for remodelling ?

- Experimental evidence for induction different host response
- Non-cross linked materials
  - Poor early tensiometric resistance
  - Also disrupt more easily in the implant
- Cross linked
  - Stronger on tensiometry
  - Occasional degradation and loss of elasticity

Ideal biomesh not designed yet

Clinical data – anterior compartment

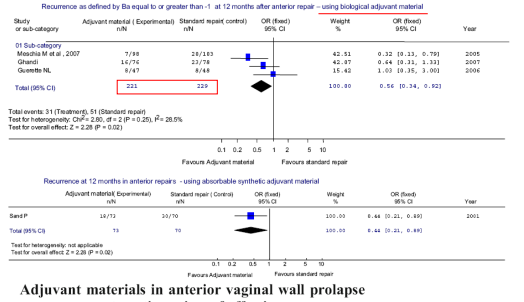
	N	Product	Follow up
Leboeuf	19	Pelvicol	15.0 mo
Urol 2004 Consec cases	24	Ant colp	
Chaliha	14	SIS	24.0 mo
Int J Urogynaecol 2005 Case control study	14	Ant colp	
Meschia	98	Pelvicol	12.0 mo
Urol 2007 Randomized trial	101	Ant colp	

Clinical data – anterior compartment

recurrences	N	Product	Anterior Stage II	Anterior Stage III	Mid	posterior
Leboeuf	19	Pelvicol	-	6.9%	0%	0%
Urol 2004 Consec cases	24	Ant colp	-	0 %	0 %	0 %
Chaliha	14	SIS	At 6 mo significantly better for D and TVL			
Int J Urogynaecol 2005 Case control study	14	Ant colp	After 2 years no anatomic differences			
Meschia	98	Pelvicol	7%	2%	3%	3%
Urol 2007 Randomized trial	101	Ant colp	19 %	2%	3%	8%

* Ba >-1

Meta-analysis



Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications

Richard Foon · Philip Toozs-Hobson · P. M. Latthe

Int Urogynecol J (2008) 19:1697–1706

Sacrocolpopexy using xenografts

observational cohort study
consecutive laparoscopic sacropexies

- 50 xenografts
  (21 SIS , 29 pelvicol)
- 100 polypropylene
  50 before the cases
  50 after the cases

Follow up
- Yearly telephone interview (Kobashi, 1991)
- 95% clinical assessment for study (Claerhout, 08)
- POP-Q, QoL (Kings)

Claerhout et al, Europ Urol 2008

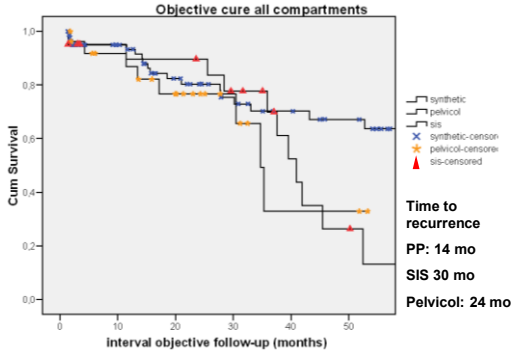
Sacrocolpopexy using xenografts

@ 32 months follow up	SIS 21	Pelvicol 29	Polypropylene 100
Objective failure (C≥-1)	22%	19%	3%*
Reoperation vault prolapse	2 (10%)	3 (10%)	0 (0%)*
Infection/exposure	2 (10%)	2 (10%)	6 (6%)
Reoperation GRC	0	1 (3.5%)	7 (7%)

Comparable demographics - no significant functional differences in prolapse, urinary, defecation and sexual function

(Deprest et al, submitted Obstet Gynecol 2008)

Sacrocolpopexy using xenografts



Time to recurrence

PP: 14 mo

SIS 30 mo

Pelvicol: 24 mo

Clinical data – vault

	N	Product	Follow up
Quiroz et al AJOG 2008	102	Pelvicol	1.1 yr
Consecutive cases Retrospective study	134	Polypr	1.1 yr
	23	Fascia	1.1 yr
Altman et al Urol 2006			
Consecutive cases Retrospective study	25	Polypr	7.1 mo
	27	Pelvicol	7.1 mo

Clinical data – vault

recurrences	N	Product	Follow up	Vault recurrence	anterior	posterior
Quiroz et al	102	Pelvicol	1.1 yr	11%* (8% reop)	7 %	3 %
Am J Obstet Gyn 2008 Consec cases	134	Polypr	1.1 yr	1%	1%	1%
Retrospective Mean follow up: 1.1 yr	23	Fascia	1.1 yr	(1/15)	0	0
				Stage II recurrence		
Altman et al	25	Polypr	7.1 mo	24%		
Urol 2006 Consec cases	27	Pelvicol	7.1 mo	29%		

Clinical data – posterior compartment

recurrences	N	Product	Follow Up	posterior Stage II*	Local problems
Paraiso et al	37	Posterior repair	17.5 mo		
Am J Obstet Gynecol 2006	37	Site specific repair			
Randomized trial	32	+SIS augment			

Conclusion

- No graft complications
- Faster and more severe failure with graft

* Bp ≥-2

Conclusions - 2

- The results are at present conflicting
  - Even RCT material typically dubious in nature
  - Variety of materials and techniques
  - Inherent short follow up with new material
- Anterior: argument for graft augmentation
  - Underpowered for functional benefit
  - Same results with synthetic material (absorable) - €
- Middle and posterior: point not proven
  - Local complications not included
  - Point at importance of long term follow up for anatomical endpoint
  - Even arguments against…

(These) materials should be used within trials

(?) PRIOR TO THEIR SALES (?)

1 **Biomaterials in Female Pelvic Floor Reconstructive Surgery**

Ajay K Singla, MD, FACS, FICS
Associate Professor
Department of Urology and Gynecology
Wayne State University

2 **Total Female Population In U.S.**

- 20 million 30-39 years
- 21.4 million 40-49 years
- 15.8 million 50-59 years
- 10.7 million 60-69 years
-
- Total procedures per year 180,000

3 **Incontinence - Incidence**

- 6.5 million women in US has SUI
- 10-35% of women 15-54 years age
- 30-50% of women over 60 years age
- 15-20% of women with recurrent SUI
- 15-20% of women with urge incontinence or other dysfunction following surgery
- De novo urge incontinence in 10%-30%
- Bladder outlet obstruction in 2.5%-24%

4 **Cost of Incontinence**

- $23.9 billion for evaluation & treatment
- $4.2 billion for Home Health Care associated with incontinence
- Total of $28.1 billion spent on incontinence in 1995 in United States
-

5 **SUI Surgery Prevelance**

- prevalence of in-patient SUI surgery US [1]
  - 48,345/yr 1979
  - 135,000/yr 1998
  - 103,467/yr 2004

- ASC visits for SUI [2]
  - 15/100,000 1994
  - 34/100,000 2000

6 **Prevelance of Pelvic Organ Prolapse (POP) Surgery**

- prevalence of vaginal prolapse surgery US [1,2]
  - >200,000/yr
  - 29% reoperation rate within 4 yr

- Life time risk to undergo surgery for POP/SUI
  11.1% [2]

7 **Science Behind Biomaterial Use**

Pelvic organ support & Continence rely on:

- Endopelvic fascia
- Ligament support
- Pelvic floor muscles

8 **Biochemical basis for Pelvic floor support**

connective tissue fibroblast

collagen type I & III

compliance

elastin tensile strength & flexibility

fiber stabilization

cross linking proline & hydroxyproline amino acids

9 **Science Behind Biomaterial Use**

- Decrease in total collagen content in women with POP and SUI as compared to controls1
- Increase in matrix metalloproteinase (MMP) – a collagen degradation enzyme
- Decrease inhibitors of MMP expression in vaginal tissues
- Increase in degradation of elastin in women with POP and SUI
- Decrease in alpha1-antitrypsin mRNA level – elastin degradation inhibitor

10 **Historical Perspective**

- Goebel 1910 Pyramidalis Ms
- Price 1933 Rectus fascia (attached)
- Aldridge 1942 Rectus fascia strips (paired)
- McGuire 1978 Rectus fascia
- Blavais 1991 Fascial strip (free)
- Beck 1988 Fascia Lata
- Raz 1989 Vaginal wall
- Handa 1996 Cadaveric fascia Lata

11 **Types of biomaterials**

- Absorbable
  - Autograft (autologous)
  - Allograft
  - Xenograft
  - Absorbable synthetic mesh
-
- Non-absorbable
  - Synthetic mesh

12 **Autograft**

-
- Rectus fascia
- Fascia lata
- Rectus muscle
- Gracilis muscle
- Vaginal mucosa

13 **Allograft**

- Fascia lata
  - FasLata
  - Suspend

- Dermis
  - Urogen
  - Axis
  - Repliform
  - Dermal Allograft

14 **Xenograft**

- Porcine dermis
  - DermMatrix
  - Pelvicol
- Porcine SIS
  - Stratisis
  - FortaFlex
  - FortaPerm
- Bovine pericardium
  - Veritas

15 **Types of Synthetic Mesh**

- Absorbable
  - Vicryl (polyglactic acid)
  - Dexon (polyglycolic acid)
- Non-absorbable
  - Nylon
  - Silastic
  - Dacron (mersilene)
  - Marlex
  - Gore-Tex
  - Prolene

16 **Synthetic material**

- Pore size (macroporous vs microporous)
- Construction (monofilament vs multifilament)
- Weave (woven, knitted, thermal bonded)
- Flexibility or elasticity
- Additives or coatings (silicone, antibiotics, collagen)

Most meshes manufactured for sling surgery are:
Monofilament, loosely woven or knitted, elastic, macroporous polypropylene (standard of care)

17 **Classification of Synthetic Mesh**

- Type I – macroporous / monofilament
  - Atrium, Marlex, Prolene and Trelex

Type II – microporous / multifilament
Gore-Tex

Type III – macroporous with multifilament
Teflon, dacron (mersilene), woven polypropylene and PTFE

Type IV – Mesh with submicronic pores coated with silicone
silastic, cellgard, dura substitute

18 **History of Cadaveric fascia**

- More than 200,000 soft tissue allograft transplants done annually in US

- Cadaveric fascia has been in clinical use for 3 decades
- Ophthalmological uses
  - Orbital floor reconstruction
  -
- Orthopedic uses
  - Anterior cruciate ligament repair

19 **Donor Screening**

- HIV 1&2 Ab
- Hepatitis B Ag & Ab
- Hepatitis C Ab
- HTLV 1/11 Ab
- Syphilis
- HIV DNA by PCR
-

20 **Tissue Processing**

- Most common: Freeze dried (Incubation in 70% isopropyl alcohol→ Frozen→gamma irradiation @ 25 Kgy)
- Freeze dried (Urogen, FasLata,Dermal allograft, Stratisis, Repliform
- Fresh Frozen (DermMatrix, Stratisis)
- Solvent dehydrated and gamma irradiated (suspend and axis tutoplast)
- Cryopreservation and amorphous freeze drying (Repliform)

21 **Processing and Strength**

- Sutaria and Staskin:
-
  - Comparison of tensile strength between freeze dried alone, freeze dried and gamma irradiated, solvent dehydrated-gamma irradiated
  - No stastical difference was noted using tensiometer

J Urol 163A 1194,2000

22 **Tissue strength**

- Lemer et. Al:
  - Maximum load to failure (MLF), stiffness assessed in autologous, freeze-dried, solvent dehydrated fascial grafts and dermal graft using tensiometer
  - MLF and stiffness equivalent in autologous and solvent dehydrated fascial graft and dermal allografts
  - Freeze dried allografts had lower MLF and were less stiff

Neurourol 18:497,1999

23 **Tissue Strength**

- Choe et.al:
-
  - Comparison of tensile strength (MLF) between allograft (freeze-dried gamma irradiated cadaveric fascia lata, cadaveric dermis), autologous (dermis, rectus fascia, vaginal mucosa) and synthetic (Gore-tex and prolene) mesh using tensiometer.
  -
  - Cadaveric fascia lata >cadaveric dermis >Gore-tex >prolene >human dermis >human rectus fascia >vaginal mucosa.

UROLOGY 58(3),2001

24 **Safety of Cadaveric tissue**

- Risk of HIV transmission from blood transfusion
  - 1/400,000 to 1/600,000
- Risk of HIV transmission from donor tissue
  - 1/1,667,600
- One documented case of HIV transmission from bone allograft in 1985

25 **Safety of Cadaveric tissue**

- Prions ("slow virus"):
  - Naturally occurring protein molecules located in CNS
  - PrPc prions are mutated due to infectious agent
  - Originally discovered after cannibalistic tribe in New Guinea found to die from progressive destructive brain disease.

26 **Prion diseases**

- Kuru Primates
- Creutzfeldt-Jacob Primates
- Scrapie Sheep
- BSE (mad cow) Cattle
- vCJD (injested tainted beef) Man
- Risk of transmission unknown

27 **Prion diseases**

- No known cure
- Inactivation is resistant to
  - Heat exposure
  - Gamma irradiation
- Alkaline treatment is thought to inactivate prions

28 **Bacterial Contamination**

- Study of 36 women undergoing cadaveric fascia lata sling
  - Cultures of allograft sent immediately prior to surgery:
  - 5/36 grew organisms
  - One developed superficial wound infection
  - Clinical significance of these findings unclear

Gerber, et.al,Urol 163A:735,2000

29 **DNA contamination**

- 4 different types of human fascia lata allograft, all processed by 4 different techniques extracted for DNA content.
- Total DNA concentrations ranged from 0.3 – 3.0 mcg/mg tissue

Sadhukhan et.al. J Urol 161A:396,1999

30 **Tissue Reaction**

- 30 female rabbit bladders exposed to
  - Synthetic sling vs. cadaveric fascia vs. control
  -
- Histologically examined at 6 and 12 weeks

31 **Tissue Reaction**

32 **Cadaveric fascia failure**

- 12 women failed cadaveric fascia (12%)
-
  - Allografts were freeze dried and irradiated
  - 3x10 cm strips used for PVS in 35 women
    »6 failed (1 week to 4 months)
  -
  - 6x 16 cm strips used for sacrocolpopexy (67)
    »6 failed (7–11 months)
  -

Fitgerald, et.al, Am. J. Obstet. Gynec.181:1339,1999

33 **Cadaveric fascia failure**

- Findings at re-operation:
-
  - Graft remnants found in 7 patients
    »Often thin and attenuated
-
  - No tissue found, only suture in 5 patients

34 **Cadaveric fascia failure**

- Histology:
  - Some areas with appropriate remodelling, linear orientation of fibrocytes within connective tissue, except high tensile strength
-
  - Other areas haphazardly arranged, non-inflammatory scar- like tissue, some areas with inflammatory response, still other areas with tissue degeneration.

35 **Allograft Concerns**

- Transmission of bacterial or viral disease
- Transmission of prions
- Durability
- Degradation of allograft
- Inconsistent quality from some tissue banks
- Cost
- Depletion of tissue banks
- Increased operative time and patient morbidity
- Unpredictable host response

36 **Synthetic Material**

- Type of Material:
- Monofilament
  - Prolene
- Multifilament
  - Mersilene
  - Gore-tex

*Bacteria enter into multifilament
*Macrophages and PMN's cannot

37 **Synthetic Material**

- Pore Size:
-
  - Larger pores > tissue bonding
  -
    - »Prolene > mersilene > marlex > Gore-tex

38 **Synthetic Material**

- Advantages:
  - Abundant – "off the shelf"
  - Decreased operative time
  - Durable – permanent
  - Cost – inexpensive
  - Independent of tissue re-modeling
  - Resistant to degradation
  - Long term preservation of tensile strength
- Risks:
  - Infection
    - »Prolene 0-3%, Mersilene & Gore-tex 5-23%
  - Erosion
  - Failure of remodeling

39 **Ideal Material**

- Biocompatible
- Acellular
- Abundant collagen
- Abundant elastin
- Preserved extracellular matrix
- High tensile strength
- Durable
- Free of Infection and erosion
- Inexpensive

40 **Applications In Urology**

- Sling surgeries in women for SUI
- Sling surgeries in men for SUI
- Pelvic floor reconstruction in women
- Urethral reconstruction in men
- Penile reconstructive surgeries
- Bladder reconstruction/replacement ?

41 **Future Sling Materials**

- Hybrid Sling Materials
-
  - Combination of allograft and synthetic material
  - Combination of xenograft and synthetic material
-
- Engineered Tissues
-

- Cells grown in tissue culture on matrix to create sling
- Myoblast taken from muscle biopsy from the patient

42

43 **Methodology**

- We evaluated 4 different sling materials
  - Small intestinal mucosa (SIS) (Cookbiotech)
  - Fascia lata (FL) (Coloplast Corp)
  - Fascia dermis (FD) (Coloplast Corp)
  - Pelvicol (P) (C.R.Bard)
- All currently used in patients clinically

44 **Methodology**

- Biomaterial was implanted intraperitoneally at the bladder neck of female Balb/c mice (n = 64)
- Animals were sacrificed at 2, 4, 8, or 12 weeks post-implantation
- Bladder and implants were extracted and fixed for histological analysis

45 **Methodology**

- Implant Histological Analysis:
  - Cell Count (cells/um^2)
  - Cell Morphology (aspect ratio)
  - Capsule formation (collagen deposition)
  - Capsule thickness (um)
  - Angiogenesis (CD31)
  -

46 **Capsule Thickness:**
2 Weeks Implantation

47 **Capsule Thickness:**
12 Weeks Implantation

48 **Cell Number**

- None of the implants displayed a significant change individually in cell number during the 12 weeks
- However, Pelvicol had significant decrease in cell number as compared to all other groups

49 **Cell Morphology**

- Aspect ratio correlates with cell morphology
  - Smaller round cells indicate inflammatory cells
  - Longer cells indicate a fibroblastic type of cell
- At specific time points there was significance between groups
- However, no implant had a significant change over the 12 weeks

50 **Capsule Thickness**

- Capsule thickness generally measures the severity of the inflammatory response
- SIS was the only group to show a significant decrease in capsule thickness over 12 weeks
- P had thinnest capsule at all time points
-
-
-

51 **Capillary Formation at 12 Weeks**

52 **Angiogenesis**

53 **Summary**

54 **Conclusion**

- Important for a graft to become incorporated as endogenous tissue and not lead to encapsulation
  - Angiogenesis allows for cells and nutrients to enter the matrix and ultimately implant survival.
  -
- At 12 weeks, SIS demonstrated minimal implant encapsulation and complete cell infiltration throughout the implant
  - Indicating improved biocompatibility as compared to the other tissues

55 **Conclusion**

- In comparing biological tissues for pelvic reconstruction we were able to assess the biocompatibility within the urological environment
- Through commercial processing, tissues are claimed to be devoid of cells
  - However, other antigens may be present which elicit inflammatory reactions, thus limiting the implant incorporation and use for long term urological therapies.
-

56 **In Vivo comparison of biomaterials in rabbit model**

- Cadaveric fascia lata
- Porcine SIS
- Porcine dermis
- Autologous
- Polypropylene mesh

57 **In Vivo comparison of biomaterials in rabbit model**

- Tensile strength (force required to break)
- Stiffness (force required to stretch sling)
- Shrinkage (% decrease in surface area)
- Distortion (ratio of the area of sling to the area of its minimal enclosing rectangle-rectangular fit factor)

58 **In Vivo comparison of biomaterials in rabbit model**

- At 12 weeks tensile strength and stiffness were greatly decreased from baseline in all materials except polypropylene mesh and autologous fascia.
- Polypropylene mesh gained stiffness with time.
- Autologous fascia and SIS experienced significant shrinkage at 12 weeks.

- Autologous fascia became highly distorted at 12 weeks.

59 **conclusions**

- Significance of tensile strength is unknown
- Stiffness is more important than tensile strength.
- The stretching of a sling with time is more likely scenario than breakage and may be responsible for the recurrence of incontinence
- Low tensile strength may explain difficulty in manipulating sling tension for recurrent incontinence
- Stiffness of mesh increased with incorporation of surrounding tissue
- The biomechanical results support the use of polypropylene mesh for sling surgery relative to other non-autologous materials.

60 **NICE Review**

61 **Objective Failure Rate**

62 **Objective Failure Rate**

63 **Failure rate for anterior prolapse**

- No mesh – 28.8%
- Synthetic non-absorbable mesh – 8.5%
-
- "The objective failure when using non-absorbable synthetic mesh was significantly lower than without mesh/graft"

64 **Low Rate of Erosion**

65 **Erosions**

- Clearly a risk – 10% in literature
- With better surgical technique/more care with the vaginal wall dissection current studies demonstrate a much lower incidence – 2-5%

66 **How well do we do with traditional prolapse repairs?**

- Randomized trial
- Median follow up of 23 months
- Findings – Success rates
  - Anterior plication – 30%
  - Plication with absorbable mesh – 42%
  - Ultralateral plication – 46%
- Many of these did not require further repair
- But - What will happen at 5 or even 10 years?

67 **Why such a high failure rate?**

- Tissue Factors
  - Multiple studies show differences in tissue between women with prolapse and those without – vaginal tissue, skin and other sites
-

68 **Why such a high failure rate**

- Tissue Factors
  - Multiple studies show differences in tissue between women with prolapse and those without – vaginal tissue, skin and other sites
-
- Thus – are we really helping by suturing weakened, possibly defective tissue back

together?

■

69 **Paradigm of General Surgery: Hernia Repairs**

- For decades inguinal and abdominal wall hernias were repaired by suturing native tissue to native tissue
- ■
- More recently many have started to use synthetic mesh with improved results
- Can we follow this paradigm?

70 **Mesh Repair - Kits**

71 **Outcomes**

- National Institute for Health and Clinical Excellence (NICE) report
  - Provides national clinical guidelines in the United Kingdom
- Examined surgical repair of vaginal prolapse using mesh
- 199 page document
- Evaluated 446 reports - 49 studies selected
- 4569 patients in total

72 **Poor Surgical Outcome with Allograft**

73

74

75

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78 **Failure of Allograft**

- Variable host response
- Method of tissue processing
- Site of harvest
- Quality of harvested graft

79 **Small intestinal submucosa (SIS)**

- Prepared from submucosa of small intestine of pigs and is replaced by host tissue in 90-120 days
- SIS contains
  - Collagen
  - Growth factors
    - Transforming growth factor- alpha
    - Fibroblast growth factor-2
    - Glucosaminoglycans
    - Glycoprotein
- Minimal tissue reaction
- Biocompatible
- High tensile strenghth

80 **SIS in Pubovaginal Sling**

Literature Review

- Total Patients 152
- Follow-up time 4 yrs
- Cured 142 (93.4%)
- Improved 3 (1.98%)
- Failed 7 (4.06%)

81 **Our Experience with SIS**

-
- Total patients 22
- PVS (4-PLY) 15
- PVT (8-PLY) 6
- Male Sling (4-PLY) 1

82 **Our Experience with SIS**

- PVS
  - Cured 12
  - Improved 2
  - Failed 1
- PVT
  - Cured 3
  - Improved 1
  - Failed 2
- Male Sling
  - Cured/Improved 1

83 **What Do I Use**

- Hypermobility
  - Polypropylene mesh (TOT)
  - ISD
    - First time – SIS pubovaginal sling
    - Re do - Autologous fascia
  - POP
    - vaginal – allograft
    - sacrcolpopexy – polypropylene mesh

84 **FDA Regulation**

- FDA classify all implantable devices into 3 regulatory classes based on the degree of regulation necessary to provide device safety and effectiveness. (1976 amendment)
- Sling materials are included in class II devices and are subject to general controls and special controls. It requires data from human clinical trials, post-market surveillance, patient registries. (1990 amendmend)

85

- Biomaterial – Any natural or synthetic substance that incorporates or integrates into patients tissues.
- Biocompatibility – Ability of a material to perform with an appropriate host response in a specific situation.
  - It needs to be integrated properly into the tissues
  - Generate an appropriate inflammatory response
  - Maintain mechanical integrity (hold shape)
  -
-

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88 **Criteria for Ideal Synthetic Sling**

1. The material should be chemically inert.
2. Not to be modified by tissue fluids.
3. Not induce inflammatory response or antibodies.
4. Not be carcinogenic.
5. Not induce allergy or hypersensitivity.
6. Be able to resist mechanical stress.
7. Be manufactured in the required shape.
8. Be able to be sterilized.
9. Resistant to infection.
10. Be resistant to adhesions.
11. Have a better in vivo response than autologous tissue.
12. Cost effective

1.

Clinical results of biological and synthetic graft use in pelvic organ prolapse surgery

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Pelvic floor dysfunction associated with prolapse is a common disorder affecting a substantial number of women in almost every population. It may occur in up to 50% of paraous women (1,2). Seven to 11 % of women will undergo surgery for prolapse during their lifetime and 29 to 30 % of those may require repeat operation for recurrent prolapse (3,4). Surgical cure rates vary depending on the technique used. Originally described traditional repair techniques, the anterior and posterior repairs, rely on adequate tissue for successful repair. Thus, use of attenuated or weak tissue for primary repair may provide poor results (5). In an attempt to improve prolapse surgery outcomes, several biological and synthetic materials have been used during pelvic reconstructive surgeries.

Any natural or synthetic substance that incorporates or integrates into a patient's own is defined as a "biomaterial" (6). The biomaterials or grafts used in pelvic reconstrucitve surgeries are classified into two basic types: biologic and synthetic. Further types and characteristics of these materials are summarized in Table 1.

Table 1. Types of materials or grafts used in pelvic organ prolapse repair (5,7,8).

A. Biologics:

1- Autologous fascia: Rectus fascia, fascia lata, vaginal mucosa, skin graft

2- Heterologous:

i) Allogenic: Cadavaeric- Dura matter, Rectus sheath, Fascia lata, Dermis,

ii) Xenogenic: Porcine dermis, small intestine submucosa, bovine pericardium, fetal bovine dermis.

B. Synthetics:

1- Absorbable: Polyglycolic acid, polyglactin, polyglactin/polypropylene

2- Non-absorbable: Polyester, polytetrafluroroethylene (PTFE), polypropylene, Polyethylene, and nylon

The aim of using either biological or synthetic grafts is to provide adequate support to pelvic floor by reinforcing existing tissue. This is one of the main indications for graft use in pelvic reconstructive surgery. Other common indications: nonexistent or suboptimal autologous tissue, connective tissue disorder, unavoidable stres on the repair, the need to bridge a space, concern about vaginal length or caliber, and pelvic floor denervation, patients who failed previous surgery (4). On the contrary, pelvic radiation, poorly controlled diabetes, severe vaginal atrophy, and predisposition to infection such as systemic steroid use, active vaginal infection and heavy tobacco use are termed to be contraindications for use of graft materials in pelvic organ prolapse repair (4,9).

Development, processing and characteristics of prosthesis are beyond the scope of this review and will be discussed elsewhere in this course. In this review, it was aimed to provide available data about the efficacy and clinical use of biological or synthetic grafts in pelvic organ prolapse treatment.

Clinical Results:

Recently, it was reported that nearly half of the surgeons used minimally invasive transobturator devices for cystocele repair and nearly all use synthetic mesh in procedures either for stress incontinence and/or POP treatment (10). Dissatisfaction with traditional repairs has led to more frequent use of grafts. Long-term success rates with biologic or synthetic mesh were reported to be between 68-100% for abdominal sacrocolpopexies (ASC), ranged from 84 to 100% for posterior repairs. Success rates are not consistent for anterior repairs (2,11). Since there are only few prospective, randomized controlled studies evaluating the success rates and complications of graft use in pelvic reconstructive surgery, it’s not possible to make definitive conclusions. Recently published studies involving different types of grafts used in vault apical, anterior and posterior prolapse surgery will be addressed in this review.

Apical prolapse

Abdominal sacrocolpopexy using synthetic mesh is defined as the "gold" standard treatment for apical vaginal prolapse (8,12). Success rates for this procedure range from 78 to 100% over a follow- up period of 6 months to 3 years (13). Longer term follow-up data is also available in another study and for up-to 13 years after ASC, 74% success rate was maintained (14). Laparoscopic sacrocolpopexy was also shown to have similar short-term outcomes comparable with the abdominal approach (7). Operative outcomes with follow-up periods with use of different mesh types are consistently high in ASC and are listed in Table 2. However, allogenic graft material use in ASC showed a high short-term failure rate (15). In two prospective trials comparing treatment succces of synthetic and biological meshes for ASC, Culligan et al reported significantly higher failure rates in women receiving solvent dehydrated fascial grafts at 6^{th} months postoperatively compared to women receving synthetic mesh (16). Similarly, use of synthetic mesh was also found to be superior to use of freze-dried cadaveric fascia for ASC surgery in a retrospective cohort study. Higher success rates were obtained when mesh was used (89%) compared to allograft use (61%) (17). On the contrary, Fitzgerald et al, reported on a series of 67 women who underwent ASC with cadaveric fascia lata and determined failure of the procedure in 8% at a follow-up period of 6-11 months (15).

Table 2. Operative outcomes with use of different mesh types in abdominal sacrocolpopexy.

Author	n	Mesh type	Follow-up (mo)	Success (%)
Gregory et al (17)	28	Marlex/Mersilene	26.3	89
Culligan et al (16)	54	Polypropylene	12	91
Altman et al (18)	25	Prolene	7.4	71
Rust et al (19)	12	Mersilene	9-42	100
Addison et al (20)	56	Mersilene	6-126	89
Baker et al. (21)	59	Prolene	1-45	86
Tate et al. (22)	29	Polypropylene	60	93
Granese et al. (23)	131	Polypropylene	43 mo	94.9
Fox and Stanton (24)	29	Teflon	6-32	100
Snyder, Krantz (25)	147	Gore-Tex	60	73
Valaitis, Stanton(26)	43	Teflon	3-91	91

Treatment of apical and vault prolapse may also be carried out by transvaginal route. Benson et al., treated 88 women by randomizing to a vaginal (bilateral sacrospinous vault suspension and paravaginal repair) or abdominal (sacrocolpopexy and paravaginal repair) surgical technique. The treatment outcome was considered as unsatisfactory in 33% of the vaginal group and 16% of the abdominal group (27). In another study comparing two techniques optimal results were obtained in 80.3% of women in the vaginal group and 94.2% in the abdominal group (28). However, Maher et al, after 2 years of follow-up, reported equal treatment successes as 91% and 94% in vaginal and abdominal sacrocolpopexy groups, respectively (29). Considering these three trials which were considered to be similar enough to allow comparison of these two techniques revealed that ASC was better than vaginal treatment in terms of: a lower rate of recurrent vault prolapse, less postoperative dyspareunia, less postoperative stress incontinence, lower reoperation rate for prolapse (27-29).

Posterior intravaginal sling (PIVS) or intravaginal slingplasties using synthetic mesh are other alternatives for the treatment of apical vault prolapse (8). Petros first described this technique as a less invasive method and reported a succcess rate of 94% in 71 patients with 5.6% complication rate (30). Literature consists of several studies with intravaginal slingoplasties that have used nylon, polypropylene, polyglactin/prolene and prolene meshes and success ranged between 71%-100% (8). In another study, 118 consecutive women underwent PIVS operation for Pelvic Organ Prolapse Quantification stage 3 or 4 vaginal cuff prolapse. At a mean follow-up of 58.6 months, the success rate of PIVS was 96.6% (31).

For sacral colpopexy using polypropylene graft, mesh erosion or extrusion rates were reported to be around 2% as suggested by IUGA/ICS (5,32). These rates were found to be higher with microporous, multifilament meshes such as Gore-Tex and Mersilene (33). Nygaard et al., reviewed 2178 women who underwent ASC and reported 3.4% erosion. Erosion rate was highest for Teflon, Marlex and Gore-Tex (appr. 5%) whereas, it was less

than 1% for prolene (13). Gastrointestinal complications such as ileus and small bowel obstruction may also be detected after ASC operation. Women were reported to experience 5.9% ileus or small bowel obstruction with 1.2% of patients requiring operation (34). However, there's enough support in literature for the use of polypropylene mesh. Thus, as National Institute of Health and Clinical Excellence recommends, polypropylene mesh use in ASC surgery may be termed as a safe and efficacious method of vaginal vault prolapse repair (35).

Anterior compartment

Traditional treatment of anterior vaginal prolapse with patient's native tissue (anterior colporraphy) has been reported to have a high failure rate both for primary and secondary cases (35). The risk for failure after classic anterior repair was found to be 30% within 4 years of the original surgery (36) and several other prospective studies have demonstrated that anterior colporraphy alone has a success rate of 37% to 57% (37,38). Synthetic and biological materials at the time of anterior repair are used in order to improve outcomes of this surgery.

Although synthetic grafts are widely used in the treatment of anterior repair, the majority of the reported studies are retrospective case series and success rates are highly different (8). These differences occur since authors use distinct definitions for outcomes, success and use different materials. Moreover, classification of anterior prolapse and treatment are not standardized in every study. Nevertheless, anatomic cure rates using polypropylene meshes and new prosthetic kits ranges from 75.7% to 100% (35). Sand et al, in their prospective randomized study, compared use of polyglactin 910 mesh placed during anterior repair to classic treatment. They concluded that mesh reinforced treatment had significantly lower recurrence rate compared to controls (25% vs 43%, P= 0.02) (37). Most studies use "tension-free" technique for transvaginal mesh placement. De Tayrac et al., had a success rate of 89.1% in 55 women with graft placed anterior repair. Mesh related

complications occurred in 14.6% of patients with 9.1% mesh extrusion (39). Similarly, Hoenil et al., and Deffieux et al, used commercially available tension free kits and reported 94.5% and 94.3% success rates, respectively (40,41). However, mesh extrusion rates in the latter study was found to be 20% (41). Considering the efficacy of recurrent cystocele, 24 women allocated to anterior colporraphy alone or reinforcement with mesh. Authors anchored the prosthesis proximally to the vaginal apex and laterally to the levator fascia after standard colporraphy and at 24 months' follow-up, prolapse treatment was 100% in the mesh group whereas, it was 66% in women who received anterior colporraphy alone (42). In a prospective observational study, Milani et al found 94% success rate with Prolene mesh at a 17-month follow-up, but there was an erosion rate of 13% (43). Salvatore et al, reported a similar complication rate with 13% erosion and a significant increase in overactive bladder symptoms (56%), dyspareunia (78%) after mesh placement (44). In ten randomized controlled studies (1148 women), it was shown that mesh/graft use for anterior repair was beter than no mesh for preventing recurrence (45). Thus, nonabsorbable mesh use for anterior prolapse repair is accepted to have high success rates but seems to have unacceptably high complication rates in some series (5).

In an attempt to decrease the complication rates and particularly erosions, biological grafts were introduced for anterior repairs. In terms of biological materials, Salomon et al., reported anterior prolapse repair using porcine dermal implant through the transobturator route. Anatomical cure was present in 81% of women whereas 19% had recurrence or persistence (46). In a retrospective review, Gomelsky et al, 70 women underwent surgical repair of high grade cystocele with porcine dermis interposition grafts. The graft was secured to arcus tendinous fascia pelvis (ATFP). More than 90% of patients had no failure at a mean follow-up of 24 months (47). Using same graft for the correction of advanced anterior vaginal prolapse, a 4 x 12 cm segment was secured bilaterally to the ATFP. At 2 years followup, an

overall cure rate of 78% was reported (48). Systematic review and meta-analysis for using mesh or grafts in the treatment of anterior compartment prolapse revealed the evidence that there was a trend in the crude objective failure rates with procedures not using mesh/graft having the highest failure rate, followed by procedures with absorbable synthetic mesh, biological graft, and non-absorbable synthetic mesh with decreasing order (45). However, Cervigni et al., compared Prolene Soft with Porcine Dermis with a mean follow-up of 8 months in anterior repair. The objective falure rates were found to be similar between groups (49).

The primary aim of using absorbable mesh was to achieve equivalent success rates with fewer complications. Polyglactin 910 has been examined in several studies and concluded that it led to significantly decreased recurrence rate compared to traditional colporraphy (5). Similarly, Maher et al., supported this finding and observed that use of Polyglactin 910 had higher cure rates when compared to fascial repair only (75% vs 57%) (50). Considering the efficacy of cadaveric tissues in anterior prolapse repair, Ghandi et al, found decreased recurrence rates with the use of cadaveric fascia lata versus standard repair (51). Kobashi et al., used cadaveric fascia lata secured by anchors attached to the pubic bone vaginally, and sutured laterally and posteriorly to the vault for treatment of primary cystocele. No failures or complications were observed at a short follow-up (52). In another study, Frederick et al., examined 251 patients and at a short follow-up (6 months), cadaveric sling us efor anterior prolapse showed 93% cure (53). However, Clemons et al, had only 59% success rate by using AlloDerm graft for anterior compartment treatment (54). Considering the comparative studies on the use of biological graft use in the anterior compartment and anterior colporraphy, a total of 4 RCT were available and two of these studies favored use of biological grafts for better results whereas, other 2 retrospective studies demonstrated no difference in outcomes (55). Thus, there’s no sufficient data to conclude whether biological

grafts offer advantages or disadvantages in anterior prolapse repair compared with traditional repair without graft. Results of various trials are summarized in Table 3.

Table 3. Outcomes with use of different mesh types in anterior repair

Author	n	Mesh type	Follow-up (yrs)	Success (%)
Chaikin et al (56)	17	Cadaveric fascia	0.6	100
Groutz et al (57)	21	Cadaveric fascia lata	1.7	100
Gandhi et al (51)	-	Cadaveric fascia	1.1	79
Chung et al (58)	-	Cadaveric dermis	2	84
Weber et al (38)	56	Polyglactin 910	2	42
De Tayrac et al. (59)	84	Polypropylene	2	91.6
Migliari et al. (60)	15	Polypropylene	1.3	75

There's currently mixed evidence to support graft use in every case with anterior compartment prolapse. Although graft reinforced anterior prolapse repair in recurrent cases were shown to have higher success rates in women whom no graft was used, there's still controversy in literature and further large prospective studies are required. Major concern after prolapse surgery is development of complications such as; mesh extrusion, dyspareunia, de novo urgency. Several retrospective or case studies showed excellent results whereas, serious complications were reported in other series (8).

Posterior compartment

The success rates with traditional posterior repairs range between 76% to 96% (5,35). Thus, it's questionable for further search for a new technique or graft use for posterior prolapse repair. There are no large series and randomized studies comparing graft versus no graft (61). Moreover, synthetic meshes are used less frequently, whereas absorbable meshes were not shown to have better results than traditional repair (35).

In a retrospective study, Lim et al., used polyglactin/polypropylne mesh and after 6 months of follow-up, there was a cure rate of 83.9%. The erosion rate was 12.9% in this group. Postoperative constipation was present in 18%, difficulty with defecation occurred in

20.5% and de novo dyspareunia was detected in 3.4% (62). Sand et al., randomly assigned women to receive mesh or no mesh for posterior prolapse repair. No significant improvement was detected between two groups (mesh: 91.2% vs no mesh: 90%) (37). Milani used prolene mesh both for anterior and posterior repairs and reported 6.5% erosion rate and 63% increase in dyspareunia (63).

Recently, biological materials have been introduced for posterior repairs to avoid synthetic mesh complications. In a review by Kohli and Miklos, 30 women underwent posterior repair with placement of cadaveric dermal graft and for an average of 12.9 months, 7% of patients showed failure (64). However, Altman et al., using collagen mesh had less satisfactory results. At 12 months of follow-up, 38% of patients had recurrent rectoceles (65). In a comparative study between posterior colporraphy, site-specific rectocele repair, or site-specific repair reinforced by porcine small intestinal submucosa graft, Paraiso et al, reported 86% of patients in first group and 78% of patients in site-specific repair group had anatomic cure. However, women who received graft for repair had 54% success rate (66). In another trial which compared posterior repair with or without polyglactin mesh (Vicryl), posterior compartment prolapse recurrence was equal in both groups (37).

In conclusion, currently it's not possible to make a definitive recommendation for rouine use of meshes or biological grafts in posterior compartment and native tissue even remains appropriate or same efficacy in posterior vaginal wall repair when compared to absorbable grafts (55). Moreover, there's still reluctance among many surgeons to put prosthetic material in posterior compartment because of the risk of erosion and coital dysfunction (7).

Vaginal Procedural Kits:

Although there's no evidence based suggestion for routine use of grafts or prosthesis in pelvic floor reconstructive surgeries, many different procedural kits have been developed

for vaginal placement of mesh or graft, recently. These kits include needles, mesh/graft and/or several attachment devices. Most use blind passage of needles through safe foramens or attach mesh or fix them to different anatomic locations, such as major ligaments as landmarks. These kits are developed for correction of all compartments' prolapses. Intravaginal slingplasty, anterior and posterior repairs may be carried with these kits. Prolift (Ethicon, Somerville, NJ) aims to correct anterior, posterior, or total vaginal prolapse with type I polypropylene mesh, whereas Perigee andApogee (American Medical Systems, Minnetonka, MN) employ either type I polypropylene mesh or porcine dermal graft for anterior and posterior restoration. Intravaginal slingplasty or infracoccygeal sacrocolpopexy corrects urinary incontinence and/or posterior component for apical prolapse (4). Current data related to these procedural kits are limited. Prospective randomized controlled studies are few and in limited series it was reported that Prolift^{TM} had an overall cure rate of 95.3% at 3 months (67). Gauruder-Burmester et al, applied both Perigee aand Apogee nd reported 93% rate of success at 1 year (68). In several studies, success rate for IVS was reported to range from 74% to 96% (69-71). Nguyen and Burchette reported the results of their comparative study between anterior colporraphy and Perigee with polypropylene mesh. After 1 year, success and satisfaction was obtained in 55% of patients in colporraphy group and 87% in patients who received mesh (72). In a prospective study involving 70 women, Elevate ^{TM} kit was used for prolapse repair. Twenty Anterior, 16 Posterior, and 34 Anterior and Posterior repair systems were placed. Recurrences were recorded in 21 patients (31.3%) at the 1-year follow-up. Of the 21 failures (stage ≥2), 13 were stage 2 with the leading edge above the hymen (73).

Various early complications were also reported for commercially available kits. In a series of 277 women who received Prolift (Johnson&Johnson, New Jersey, USA), a high rate of mesh exposure (12%) was reported (74). However, De Tayrac et al, reported 6.3% of vaginal erosions using Pelvitex (Sofradim, Trevoux, France) for anterior prolapse repair (75).

Similarly, Nguyen and Burchette also found low erosion rates for mesh use (5%). They also reported that de-novo dyspareunia occurred in 16% of patients receiving the kit whereas it was 9% in classic repair (72). In a recent study, evaluating the risk factors for mesh complications after trocar guided transvaginal mesh kit repair of anterior vaginal wall prolapse , mesh erosion rate was found to be 8.6%. Smoking, multiple childbirth, and somatic inflammatory disease were reported to be possible risk factors (76). Nguyen et al., evaluated perioperative complication and reoperation rates associated with slings and prolapse repairs using mesh and biologic grafts. During the 21-month period, 1508 women had prolapse repair procedures using implanted prostheses. Mesh-related reoperations after prolapse procedures were reported to be performed more often for vaginal mesh erosion (3%) than for biologic graft infection (0.3%) and were performed more commonly after anterior (6%) compared with apical (2%) or posterior vaginal mesh repairs (2%) (77).

Conclusions

Although there seems to be an increasing tendency to use of grafts in pelvic floor reconstructive surgeries, currently few studies show sufficient level of evidence. Improvement in mesh characteristics, better commercial kits may further increase their use, however long-term, randomized controlled studies are still lacking. Currently, there's mixed data to support the routine use of graft in pelvic organ prolapse treatment.

Synthetic grafts have been used for a long time for abdominal sacrocolpopexy and shown to have better results compared to biological grafts (5). The procedure is accepted as gold standard but may be associated with short term morbidity and potential foreign body problems (8).

Graft reinforcement in women with recurrent cystocele was reported to improve short term outcomes (7). Overall, insufficient data exist to conclude the superiority of anterior wall

grafts to repairs without graft use. However, nonabsorbable sythetic meshes may reveal better results at the cost of several adverse events (55).

There's limited data evaluating the role of mesh augmentation for posterior compartment prolapse repair. In many of the studies, the use of biological grafts in posterior wall repairs did not reveal better results than native tissue repair. Similarly, use of synthetic meshes did not receive enough attention because of fear of infection/erosion. There's also limited long-term data for use of biological or synthetic grafts for posterior prolapse repair.

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ICS 2012 Beijing

Complications of POP Repair

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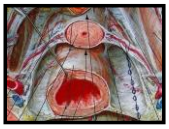
Professor of Urology
University of Campinas,
São Paulo, Brazil

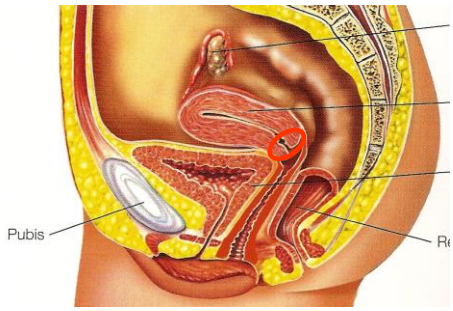
PERICERVICAL RING



- ONE OF THE MOST IMPORTANT CONCEPTS FOR
  - RECONSTRUCTIVE VAGINAL SURGEONS;
  - AT THE LEVEL OF THE ISCHIAL SPINES;
  - COMPLEX REPRESENTED BY THE CONTINUITY OF THE CARDINAL-UTEROSACRAL LIGAMENTS WITH:
  - PUBOCERVICAL AND RECTOVAGINAL FASCIA.

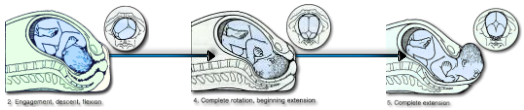
Adapted from Netter, Atlas of Human Anatomy

Pericervical Ring



Childbirth & Prolapses

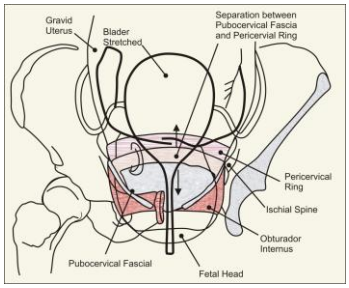
- ON THE DESCEND AND EXTENSION OF THE FETAL HEAD, INTENSE PRESSURE IS EXERTED ON THE SUSPENSORY FUNCTION OF THE UTEROSACRAL LIGAMENTS;



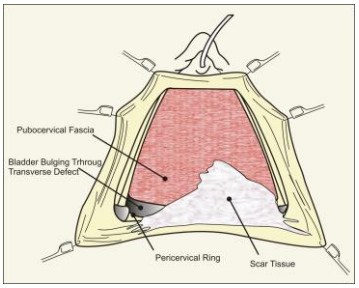
- CONTINUATION OF THIS PROCESS RESULTS IN A PROXIMAL TRANSVERSE SEPARATION OF THE RECTOVAGINAL SEPTUM FROM THE UTEROSACRAL LIGAMENT AND THE PERICERVICAL RING;

Adapted from Williams, Obstetrics

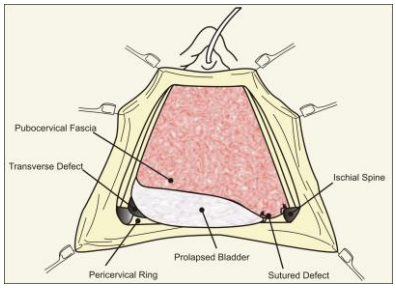
Anatomical basis



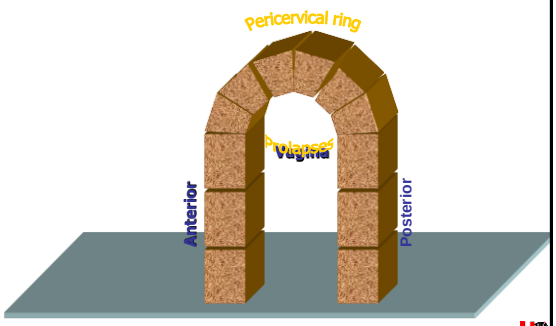
Anatomical basis



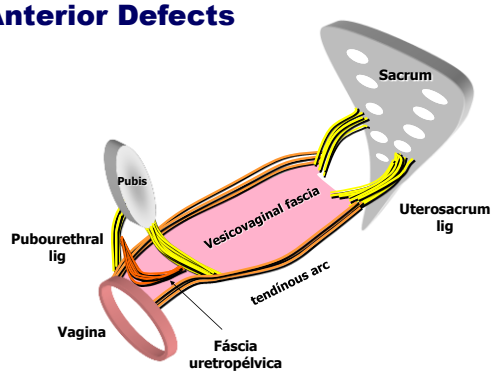
Anatomical basis



Level I Defect



Anterior Defects



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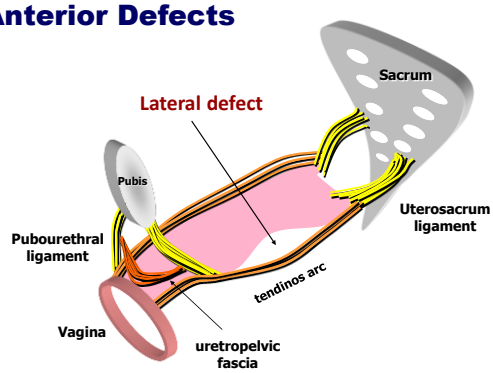
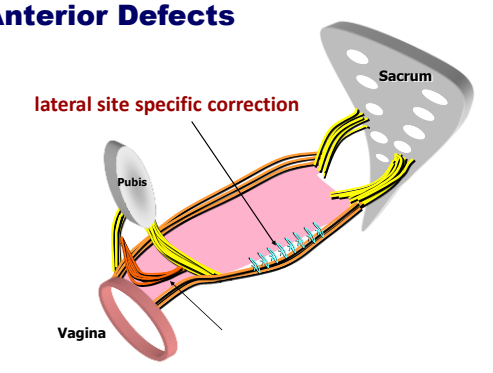
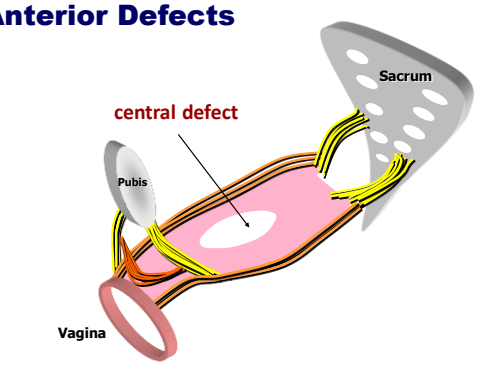


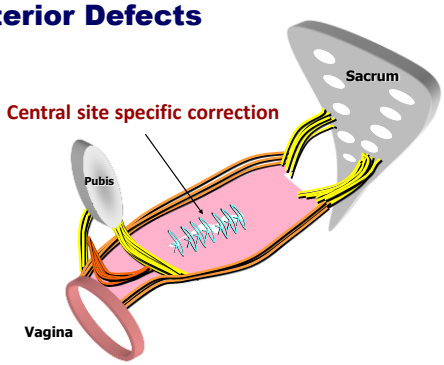
Anterior Defects



Anterior Defects



Anterior Defects



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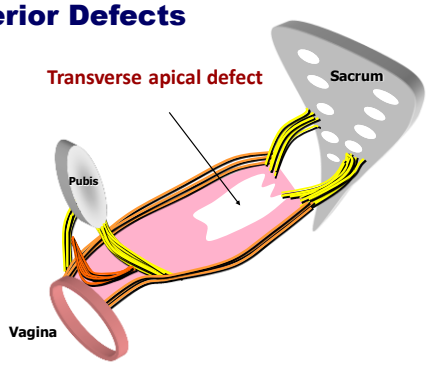
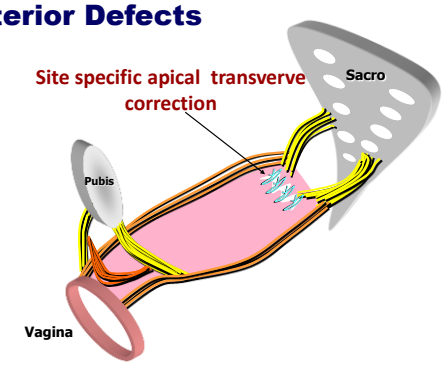
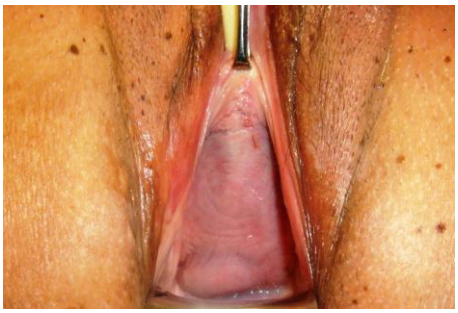


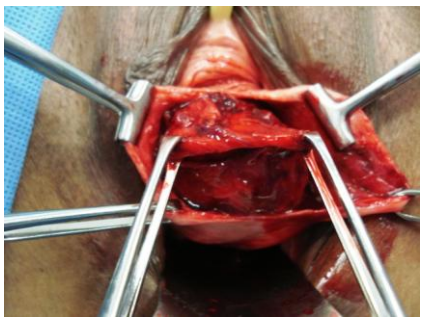
Anterior Defects



Transverse Anterior Defect



Transverse Anterior Defect



Mesh for POP repair

- High failure rates after conventional techniques
- Reinforce the native tissues ("neoligaments")
- Achieve improved functional and anatomical outcomes
- Anterior vaginal mesh: reduces the prolapse recurrence
- Posterior and apical vaginal mesh: no level I evidence to support the use

Complications (2008-2011)

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

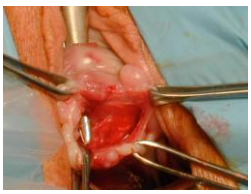
- Erosion
- Infection
- Pain
- Urinary problems
- Recurrence of prolapse and/or incontinence
- **Shrinkage of polypropylene meshes[1,2]**

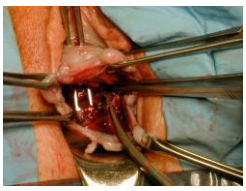
1. Garcia-Urena MA et al. Am J Surg 2007
2. Gauruder-Burmester A et al. Int Urogynecol J Pelvic Floor Dysfunct 2007

SIS: abscess

SIS: Asseptic abscess

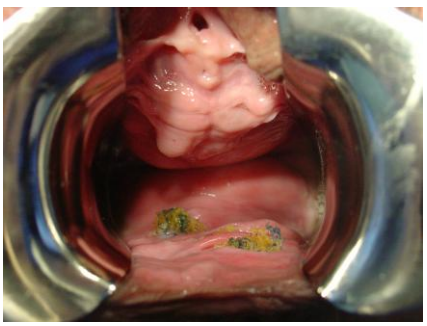
Urethrovaginalvaginal fistula





Partial removal of mesh

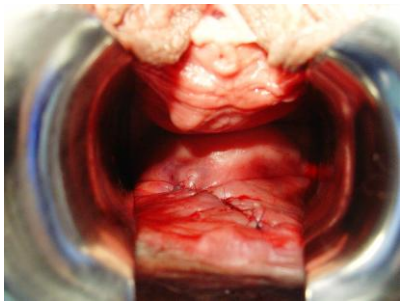
Posterior Gynemesh exposure



Posterior Gynemesh exposure

Posterior Gynemesh exposure

Posterior Gynemesh exposure



Mesh contraction

What are the clinical concerns?

Mesh contraction

Major Symptoms

- Severe vaginal pain (worsened by movements)
- Dyspareunia

Minor Symptoms

- Vaginal discharge/spotting
- Awareness of prolapse
- Male partner discomfort

Vaginal examination

- Prominent tense focal areas of mesh
  - arm / body
- Painfull prominent mesh areas
- Prominent tender band
- Vaginal tightness
- Foreshortened vagina
- Mesh erosion

Vaginal examination

Palpation of each side and arms of the mesh

↓

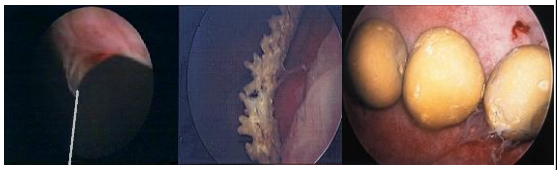
Ask if she experienced pain like during sexual intercouse or movements

↓

Localize trigger points

Perfurations

- 3,5%



Obstruction (BOO)

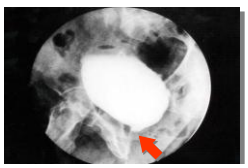
- BOO under diagnosed
- Incidence 2.7 – 23%
- Anatomical or functional
- Detrusor overactivity

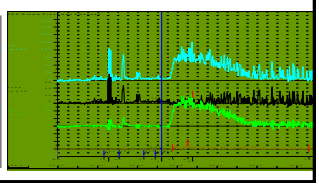
Etiology

- Anti-incontinence procedures 20%
- Genital prolapes 16%
- Primary obstruction of the bladder neck 6%

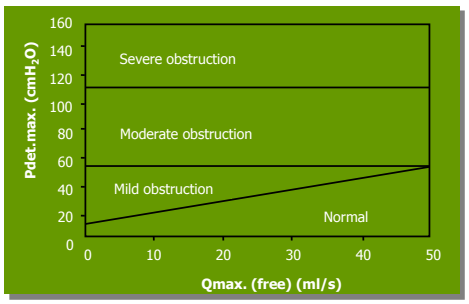
Diagnosis

➢Residuals
➢Urodinamics + VUCG
➢Videourodynamic





Nomograma



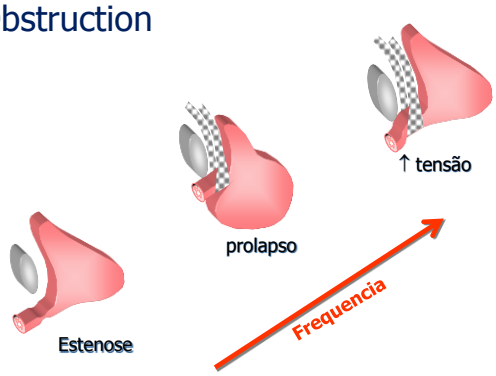
Blaivas & Groutz, 2001

BOO

1.Funcional

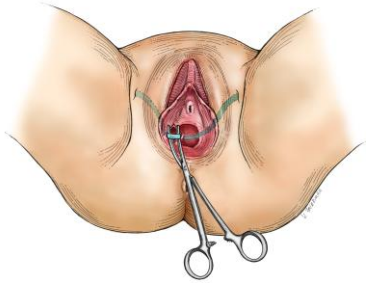
2.Anatômica

Obstruction

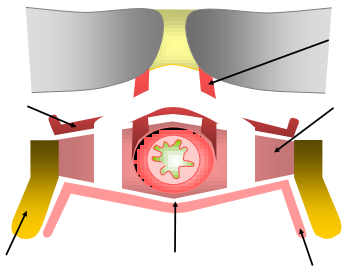


Tape incision

Partial removal



Urethrolisys



Urethrolisys :

Results

436 slings: 20 BOO (1995 - 2003)

Autologous: 18 / 210 (8,5 %)

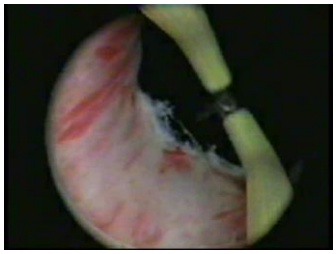
Synthetic: 2 / 226 (0,6%)

Diagnosis: from 3 m to 8 yrs. (mean: 9 m)

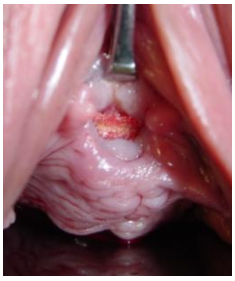
Q_{max}: 9,9 ml/s $P_{detQmax}$: 48 cmH_2O (mean)

Palma et al; Eur. Urol, 2004

TUIBN



Healing abnormalities



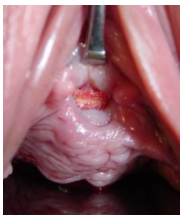
- Geralmente exposições sem granulação
- Ocorre em 6-14% casos
- Maioria assimtomatica
- Tratada conservadoramente consultório ou CC
- Influencia resultado?

Classification of healong abnormalities

	Simple	Comple
Tempo pós-op	< 12 weeks	> 12 weeks
Granulatio inflammation	Absent	Present
Localization	incision	Other
organ	Vagina	viscus

IUGA grafts symposium, 2005

Sling : healing abnormalities



Partial removal

Inside- out?

Complications- TOT

	Ob Tape	Monarc	TVT-O
Erosão	99	4	2
Infecção	22	1	1
Neuropatia	0	1	3
Dor	0	1	8
Sangramento	1	1	3
L. Bexiga	2	0	1
L. Uretra	0	0	3

Maude DB review. Hamilton Boyles, et. al. ICS 2005.

Leg pain

- **40% TVT-0**

Teo R, Moran P, Mayne C, Tincello D: Randomized trial of TVTand TVT-O for the treatment of urodynamic stress urinary incontinence in women.

2008 neurourology and urodymanics 27:572-3

Persistent pain

Conclusions

- **Mesh exposure 6-14%**
- **Conservative management first**
- **Patial removal**
- **Impact on the outcome?**
- **Severe complications - experience**
- **Prevention is the best treatment!**

Notes

Record your notes from the workshop here