Pelvic mesh, what you need to know!

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Objectives

• Describe pelvic prolapse.
• Describe urinary incontinence.
• Describe what pelvic mesh is.
• Describe the rationale behind using the mesh.
• Describe the risks and benefits of pelvic mesh.
• Are vaginal slings the same as pelvic mesh?
• Is there a role for pelvic mesh at all?
• What should you do if you have had pelvic mesh?
Pelvic prolapse

- Common gynecologic condition
- Herniation of pelvic organs such as bladder, uterus, vaginal, rectum, intestines through the vagina
- Commonly referred to as cystocele, rectocele, “dropped bladder”, enterocele
Symptoms

• Pelvic pain, pressure, bulge
• Incomplete bladder or rectal emptying
• Urinary frequency
• Urinary or fecal incontinence
• Low back pain
• Recurrent UTI’s
Normal pelvic anatomy
Rectocele
Enterocele
Cystocele
Severe prolapse
Stress Urinary incontinence

Involuntary loss of urine with activity, such as coughing, sneezing, exercising

Commonly happens with prolapse
What is the cause of POP/SUI?

ChildBirth
Genes

Risk factors:
Age
Hysterectomy
Caucasian race
Multiple births
Obesity
GROWING PELVIC MESH COMPLAINTS
PROMPT FDA WARNINGS

Bladder mesh may be unsafe for users

Users with bladder mesh might develop health concerns
“Time heals all wounds,” but money can help too.

$3.35 MILLION VERDICT IN VAGINAL MESH LAWSUIT
Vaginal Mesh Recall

Is a Vaginal mesh recall a possibility?
Find out how it causes complications.
Plaintiff attorneys seeking patients

Have you been diagnosed with severe injuries internally & have Vaginal Mesh?
You may be entitled to compensation
we can help!

FDA WARNING

July 2011
“Complications were not rare.”
“Unclear whether or not P.O.R. repair with Vaginal Mesh was more effective than traditional surgery.”

If you have suffered side effects

Lawyer@confused.com
HOW DID WE GET HERE?
Pelvic Organ Prolapse

- Up to 40% of females have POP
- About 11% of women have surgery for POP or SUI
- Numerous approaches that re-approximate native tissue
- High recurrence rates ~ 29%-40% with suture only repairs
Surgical Mesh is intended to

- Increase longevity of repair
- Restore anatomy
- Prevent recurrence
What is Mesh?

Synthetic, inert material called Polypropylene
Proven safety and track record in general surgery
Used widely for hernia repair
Vaginal Sling

In 1996 a mesh sling was introduced and revolutionized surgery for urinary incontinence.

The sling was made out of polypropylene mesh.

Minimally invasive, reproducible, outpatient, excellent results.
Vaginal sling
Pelvic mesh

- In 2000’s researchers from Europe built on mesh sling concept and developed the first generation of transvaginal pelvic mesh devices

- Initial data was very promising

- Cure for prolapse???
Transvaginal mesh
Too good to be true?

In 2005-2007 reports of complications of TVM surfaced, about 12-15% !!!

Unacceptable complications rate

FDA advisory followed
Unique Complications of Vaginal Mesh Procedures

- Extrusion of mesh in the vagina
- Erosion into the urinary tract
- Bleeding & Infection
- Contractures
- Gen pelvic pain, Sexual pain
- High rate of reoperation as a result of these complications
Vesicovaginal Fistula
Erosion into the bladder
Pain
FDA’s Public Health Notification [2008]

- Concerns for an increased rate of complications associated with the use of vaginal mesh for prolapse
FDA's update [2011]

- Serious adverse events associated with mesh use are not rare
- Transvaginal mesh placement in POP repair does not conclusively improve clinical outcomes over traditional non-mesh repair
- Reclassification to class III devices
Are vaginal slings safe?

American Congress of OBGYN, American Urologic Society, American Urogynecologic society ALL support vaginal mesh slings

Complications 2-4%

Proven long term good outcome
Minimally invasive

NO SURGERY IS RISK FREE
How about pelvic mesh? Is it safe?

 Depends on what you mean by that!

 Vaginal slings, transvaginal mesh or abdominal mesh?
Sacrocolpopexy

Longs considered GOLD STANDARD
Described in 1960
Inserted through via abdominal incision
No vaginal incision
No a transvaginal mesh
Mesh complications 0-4%
Vaginal slings are considered safe and standard of care for SUI.

Transvaginal mesh should only be used with INFORMED CONSENT when the benefits outweigh the risks.

Sacrocolpopexy remains the GOLD STANDARD repair despite using abdominal mesh.
Technique Matters!
What if you have had “pelvic mesh”

• Most complications occur within first 12-24 month
• If you are doing well, you probably continue to do well
• There is always a small chance of developing complications with time
• If you have problems with the mesh, removal may be necessary
• Most patients do very well after removal
Thank you