Top 10 Things to Know About Mesh BEFORE Having Surgery for POP or SUI

By Deb Contestabile

What if I could go back in time to before I had my mesh implant for SUI? What are the things I wish I had known? What do I think I SHOULD have been told? What do I think are the basics that everyone should know *before* they have surgery for any pelvic repairs, including POP (Pelvic Organ Prolapse), Bladder Prolapse, and SUI (Stress Urinary Incontinence)?

These are the top 10 on my list:

Top 10 Things to Know About Mesh BEFORE Having Surgery for POP or SUI

1) There are FDA WARNINGS

FDA warnings went out to doctors and the general public regarding MESH used for POP (Pelvic Organ Prolapse) in 2008, 2011, and a few news releases since then. Even though these warnings are mostly geared towards POP repairs, they also contain a lot of information regarding reported complications for SUI (Stress Urinary Incontinence). There seems to be some debate regarding the safety for mesh used for POP vs SUI. Still, in these warnings, there are specific warnings and guidelines for doctors and the general public that I would think anyone considering having TVM (transvaginal mesh) repairs would want to know, and should be made aware of.
2011-07-13 FDA NEWS RELEASE / 2011 FULL FDA warning (PDF)

In March 2013, the FDA also published "**Information for Health Care Providers for SUI**", and "**Information for Patients for SUI**". In these, the FDA suggests that patients be informed about treatment options, including non-surgical options, and surgery without mesh. They warned that mesh had the added risk of mesh erosion which could require additional surgery and cause "penile irritation and/or pain during sexual intercourse" for sexual partners.

I wish my doctor really explained to me that these **FDA warnings** existed, and that they directly pertained to the kind of surgery I was having. Not just gloss over general complications that apply to any surgery, but discuss the *SPECIFIC warnings regarding TVM*. Things like: **complications are: "not rare";** how **serious and often permanent** complications can be, and that there is **no evidence that pelvic repairs using mesh provides any clinical benefit** compared to traditional surgery.

2) The Lawsuits all over the TV are NOT just for "older", "outdated", and "no longer in use" mesh.

Unless you don't watch TV, you have probably seen the ads from lawyers regarding transvaginal mesh lawsuits. What you may not know is that many of these lawsuits are for mesh products that are still being used routinely to this day. Yet when many women ask their doctor about this they are often told, "oh, that's not what we use", "that mesh is no longer on the market", or "the mesh we use is safe". A lot of women are being told all kinds of untrue myths about mesh being safe, including that it is only mesh for POP, and NOT for SUI that is the problem. This is NOT true. Even the newest "mini-slings" are causing severe complications.

Still, many women report how their doctors will roll their eyes and tell them to stop believing what they see on TV, and by all means they should, "quit Googling things". Right. Listen… Do

yourself a big favor and find out *exactly* what kind of procedure AND type of mesh they plan to use on you BEFORE you have any surgery, and then – go GOOGLE it! AND search the FDA MAUDE database yourself. Also, check the legal section of the MDND website. There is another good article on on this from Drugwatch.

My mesh implant surgery was done was in Feb 2012, using a TOT mesh product still widely used today. It is also a product that I was shocked to discover has countless reported complications and pending lawsuits against it.

The U.S. mesh manufacturers are facing over 100,000 lawsuits in the U.S. where the majority of transvaginal meshes remains on the market.

3) Complications are "NOT RARE".

I feel the need to repeat this. A lot. I frequently hear the argument that "every surgery has risks", and many think the percentage of people who actually suffer from complications from mesh is only 1% or 2%. This is because many doctors are reporting out-dated studies that were done BY the mesh manufacturers. There are more recent studies that indicate complications as high as 36%. Of course any study can be bias, and it's difficult to know how accurate those stats are. Regardless, the FDA's July 2011 warning specifically said that complications are "NOT rare". This was a direct change and correction from their previous warning where they indicated the opposite (that complications were rare). Obviously, the stats were great enough for them to change that statement and put out the July 2011 warning.

"Not rare" is rather vague, though, isn't it? Still, it doesn't sound very promising. Who wants to take a "not rare" risk? The more I've researched the stats, the less promising they sound. The fact that there are over 100,000 lawsuits is also pretty telling. Are we to believe they are all just lawyer generated hype? What about the fact that there are even more reported complications that do not even have any lawsuits pending? Here's an update on this situation from MDND: "FDA: Stress Urinary Incontinence (SUI) Surgical Mesh Reports up 36 Percent".

4) Surgical Mesh Implants are PERMANENT

Yes, a mesh implant is permanent, or at least meant to be. The FDA stated that using mesh can "make any future surgical repairs more challenging and can put the patient at risk for additional complications and surgeries". Mesh attaches and well, *meshes* with your tissues. That's what it's designed to do. This means that if there's a problem, it is very difficult to fix because they can't usually just remove the implant. While there are a ton of doctors who know how to put mesh INTO your body, most do not know how to remove it. The mesh adheres to organs, nerves, muscles and even bones. My mesh had to be scraped off my pelvic bone when I had it removed (and no, it wasn't suppose to be there).

5) Complications are SEVERE

Complications from TVM may not normally be life threatening, but they do greatly impact one's quality of life. Because mesh is meant to be permanent, when there are complications they are not only usually severe, but also *not* easily resolved. Frequently damage done is permanent. As if that isn't bad enough, the complications can keep progressing as the mesh erodes and works its way through your tissues, organs, etc.

The complications are summed up in the FDA report, as follows:

> *"The most frequently reported complications from surgical mesh used to repair POP include: mesh becoming exposed or protruding out of the vaginal tissue (erosion), pain, infection, bleeding, pain during sexual intercourse, organ perforation from surgical tools used in the mesh placement procedure, and urinary problems. Some reports cited the need for additional surgeries or hospitalization to treat complications or to remove the mesh."*

My story has to do with my leg and mobility primarily. Not being able to walk is a problem, for sure. My whole life was thrown upside down this past year when suddenly, at 46 years of age, I felt dependent on my husband and children. This was bad enough, but, I have talked to lots of women who make my story sound like a walk in the park.

Many have chronic pain, infections, and inflammation. They have damaged bladders, colons, urethras, nerves, vaginal walls and so much more. These are major issues. Debilitating, life-changing problems, that often keep getting worse and worse and lead to surgery after surgery. Not only are mobility, pain and dyspareunia problems, but we're talking self catheterization and colostomy bags here people!

What's worse is many women with complications go undiagnosed or misdiagnosed. Some are just told to live with it.

Is not peeing when you sneeze worth these risks? Even if you need more serious repairs, and no doubt many do, is it worth these risks when you could have traditional surgery without mesh (see #8)?

For more details on the types of pain mesh can cause, check out some of these women's stories in the Patient Profiles page of MDND, videos I've found, or Linda K's blog. Better yet "chat" with some of these women yourself in one of the many forums, or Facebook Groups (mentioned to the right and bottom).

6) Mesh hardens once it's in your body, and is not inert.

They show you some picture of a cushy, gauze-like material that will be used. What I didn't know beforehand, though, was that once that material is in your body it changes dramatically. This is because it is made of polypropylene, and it hardens from your body heat into a consistency similar to a strip from your screen window. This is why it can cut, or "erode", through tissues causing damage. ("Dr. Ostergard on Degradation, infection and heat effects on polypropylene mesh")

Contrary to original beliefs about mesh, there is now evidence and medical opinions that mesh is *not* inert.

In a Federal Lawsuit Against C.R. Bard says Mesh is Not Inert, and:

> *"The **Plaintiffs** claim that the **polypropylene mesh** (monofilament) is not inert, meaning it does not lie dormant in the body and is biologically incompatible with human tissue. In a subset of the population an immune response is noted in the form of inflammation of the pelvic tissue and severe adverse reactions including, but not limited to hyper-nflammatory responses, chronic pain and fibrotic reaction…"*

In another MDND article, "Get the Mesh Out! Doctors React to Patients Following FDA's July Warning about Surgical Mesh", Dr. Donald R. Ostergard states:

> *"I gave a lecture to AUGS in 2006 on this topic and I was called a dinosaur who had his head in the sand about advances. As things have happened I feel vindicated. I wish this had been said some time ago. Polypropylene is not inert even though the manufacturers said it was inert."*
> "It's the biggest public health issue facing us now!"

"One day you have urine leakage. The next you don't. End of story."
"End of Story"?! Hardly!

7) There is "NO EVIDENCE Mesh Provides Any Clinical Benefit Than Non-Mesh Surgeries"

"NO EVIDENCE" mesh is better? That is HUGE! That is also another part of the FDA warning. Notice this warning did NOT specify a specific type of mesh, a certain manufacturer or brand. It is a very general statement and was geared towards ALL surgical mesh for POP. It means they have been fixing pelvic repairs for years using our own biological surgeries etc., and that there is ***not any proof found that using mesh has any clinical benefit***. You can read this in the FDA announcement (www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm262752.htm). You can also do a search in Google Scholar, for example, and easily pull up articles like this one: "Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse", where it concludes:

> ***"The use of mesh for anterior prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal. Native tissue and vaginal mesh surgery had similar 5-year risks for surgery for recurrent prolapse."***

However, this is not what many patients are lead to believe. Mesh was marketed as "the gold standard" of treatment for POP/SUI. Many seem to be clinging to that belief in spite of all the data and reported complications.

What are some of the common reasons still being used in support of mesh? Well, **some will say using mesh is *"less invasive".* Is it?** Patients are told there is less down time and quicker recovery time. They are led to believe it will be "quick and easy". It's an outpatient procedure. Of course, this sounds great in today's busy world. But, is it that quick and easy? Well, it's definitely quicker for the doctor to implant it. My implant surgery itself was done in less than fifteen minutes! Fifteen *months* later, however, I am still dealing with the very problematic aftermath.

To me, the "less invasive/quick and easy" idea is nothing more than an upsetting marketing strategy disguised as "helping more people". The bottom line is that IF you are one of the MANY women who winds up having some of those *"not rare"* complications- then the repercussions of that less invasive surgery are definitely NOT "quick", and anything BUT "easy".

Some will say mesh repairs last longer (than non-mesh repairs using your own biological tissue). Will it? Where is the evidence of this? There are many women, including myself, who have had to have repeat surgeries after mesh implants. Often, multiple surgeries are necessary to try to remove the mesh, and fix the further damage it caused.

Linda Gross, who recently won her first battle with Johnson and Johnson, reportedly had **18 subsequent unsuccessful** revision procedures following the initial surgery. She has described her life after surgery as a *"living hell"* and has characterized she and thousands of other women as "guinea pigs" to the vaginal mesh maker.

There is also that FDA report that completely contradicts the belief that mesh is "better". This is what that FDA warning stated:

> *"The FDA also conducted a review of scientific literature published between 1996 and 2010 comparing mesh surgeries to non-mesh surgeries. The agency review suggests that many* ***patients who undergo transvaginal POP repair with mesh are exposed to additional risks,*** *compared to patients who undergo POP repair with stitches alone. While mesh often corrected anatomy, there was* ***no evidence that mesh provided any greater clinical benefit than non-mesh surgeries."***

Think about this as well; If your transvaginal mesh surgery fails, you then have a foreign object in your body that is literally cutting through your most sensitive tissues and wreaking havoc. If your non-mesh repairs, using your own biological tissue, fails than you may still have SUI or need further repairs but, you do NOT have the problems of mesh erosion and removal which is next to impossible.

Many believe it is not the mesh, but that some *patients* are higher risks. Really? And what makes a patient "high risk"? Who decides this? What criteria are they basing that decision on? Are doctors telling patients that they are not good candidates? If I was a high risk for any reason, I was never told so. I have talked to numerous other women from

their twenties to their sixties, from all walks of life, and all shapes and sizes that have had mesh complications. Most of them claim they were not told of ANY risks, let alone that they might be a "high risk" patient.

Then, there is the argument that it's not the mesh, but it is the *doctor* implanting it that is at fault. Are they? Mesh manufacturers would like you to believe this, because that gets them off the hook, and they are the ones being sued primarily (the manufacturers, not the doctors). Many will tell you that if you go to a reputable doctor that puts the mesh in, you should be fine. Personally, I disagree. I disagree because I don't see how the product can be safe when it literally hardens and cuts through your most delicate tissues (see #6!). I've felt that pain firsthand. I've also talked to women who went to very reputable doctors for their mesh implants, and STILL had complications. One woman even stated;

*"I had an excellent surgeon place the mesh. When I was examined by a different doctor, she was visibly shaken when she saw who did the mesh placement. She referred to the surgeon by their first name and said she knew their work, and if **I** was having problems, then anyone can have problems."*

8) There Are ALTERNATIVES

Surgery should be the last resort in most medical conditions, as any surgery has risks. Non-surgical options for POP and SUI include pelvic floor therapy, and pessaries. Many women find success with these methods, yet these non-invasive options are often not even mentioned or discussed with patients prior to surgery.

When surgery IS required, women should know there are NON-MESH surgical alternatives. These are the "traditional methods" that the FDA was referring to when they said there wasn't any evidence that mesh worked any better than "traditional repair surgeries". Of course no surgery is without risks, but using transvaginal mesh brings many additional risks, like mesh erosion, to the table. Yet, many women are also never offered these non-mesh surgical options. Why? Maybe it's because many doctors that implant transvaginalmesh, do not even know how to do the non-mesh surgical repairs. The marketing of mesh as "quick and easy" comes into play again and again. Non-mesh repairs require more surgical skill and time. However, there are doctors that do non-mesh repairs, and they are worth seeking out.

Using the fascia, or your own tissue is one of the traditional non-mesh methods of surgery for SUI or POP repairs. This is what Dr. Raz, the surgeon who did my removal surgery, said he would do IF I needed it once he removed the mesh. It took some calling around, but I was able to find a local GYN who also does pelvic repairs and does NOT use mesh. Hopefully, more and more doctors will abandon mesh and use non-mesh alternatives again. Some of those alternatives are discussed in detail very well by Linda K: http://teapapers.com/bladdersling/2012/07/non-mesh-bladder-repair-surgery/

9) HELP is HARD to FIND!

If you DO have complications – please know that often the surgeon who did your implant may NOT help you. Some will not even consider that the mesh is your problem. Before my surgery, I really thought, **"if there's a problem… they will fix it".** WRONG! Who knew??

Turns out, there are a LOT of doctors who know how to put mesh in, but very few with experience at removing it. I wish I had known that the surgeon who did my implant would not help me. Not only that, but that I would not be able to find a doctor anywhere in my area that knew how to remove the mesh successfully in its entirety. Matter of fact, I was told it was "impossible" to remove all of the mesh, especially the part in my thigh/groin where my pain stemmed from. Luckily, I knew that wasn't true because I had been researching things online myself.

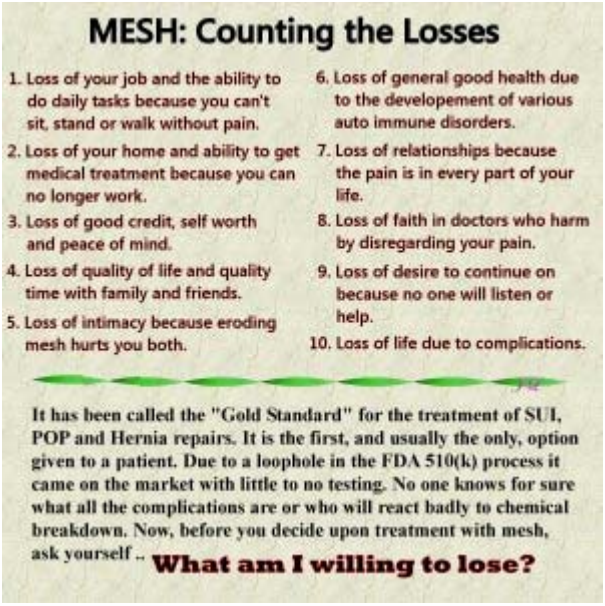
I wound up **traveling across the country, from NY to CA** to go to one of the only well-known experts that removes mesh. Actually, I believe he is THE best and so do many others – and that would be Dr. Raz at UCLA.

In addition to a shortage of specialists that are trained in removing mesh, the cost of surgery is a huge factor. Those who have health insurance, still need to cover travel expenses, and worry about in-network vs. out-of-network coverage. Many women do not even have health insurance at all because they have lost their jobs, homes, and health insurance.

10) FDA "Approved" does not mean the device was actually tested.

Prior to my own ordeal, I never thought much about the FDA – but, I believed that *"FDA approved"* meant something was safer than if it was not approved. I was shocked to learn that medical devices can be FDA approved based on the fact that a previous, similar device was tested and approved. They do not need to test each product. But, here's the really scary part - if/when an original device winds up being RECALLED or pulled from the market due to complications – they DO NOT recall ALL the many other "similar'" products that snuck in without testing on the basis of that first product. ?!? Did you catch that? It's sort of tricky to understand, but the more you do understand it, the more obvious it is that this system is seriously flawed.

For a very detailed explanation of this see the petition from Taigen Leigh, or video:
www.youtube.com/watch?feature=player_embedded&v=qCda6GK0S38



So there's my top 10 things I wish I knew about MESH before I went under the knife. There IS more. Lots more, and the more I learn, the more infuriating it all is.

When I decided to have surgery using a mesh implant for SUI, I did not put a lot of thought into it. I was busy with work and my family like the rest of the world. The surgeon and procedure were recommended to me by a good friend. I thought this would be a minor surgery for a somewhat embarrassing, and very common, problem. I went on the little information that was given to me from the doctor, and believed I would be fine in a matter of days. I believed the marketing, which is that this will be "less invasive", "quick and easy".

There was no discussion of FDA warnings, alternatives, or that I might not be a good candidate. I did not research it myself because I didn't think I needed to. It simply never dawned on me that a product would be used that had such highly reported risks. Especially not to fix a problem that literally posed no real threat.

Now that I have lived with, and researched mesh complications, I'm appalled that "they" are still marketing and using mesh at all. I'm even more appalled that there are so many women who suffer complications that were NOT given crucial information upfront. How is this possible? How can anyone make a really well-informed and good decision if they don't have the basic hard facts to go on?

If someone chooses mesh surgery AFTER they have been given those hard facts, than that is their choice and I would respect that choice, even if I didn't agree with it. However, to not even be given the opportunity to make a well-educated choice? Especially one that could potentially greatly impact the rest of your life? That is just not right.

As I have mentioned, I have talked to countless women who are in pain and agony. I am NOT exaggerating. Their lives have been torn apart, and their stories are more than a little depressing. The fact that this all seems so AVOIDABLE to me is what really gets me. It's not like mesh was used because there WAS no other options. It is being used INSTEAD of better options.

I'm all for women who have POP or SUI to come forward and get help, but when they get the courage to do so, ***help them*!** Don't ruin their lives!! Don't let manufacturers and marketing companies sell them defective products and tell them how "quick and easy" things will be when there is so much evidence to the contrary. Please don't make them find out all this information AFTER they have problems.