



Chronic Pelvic Pain

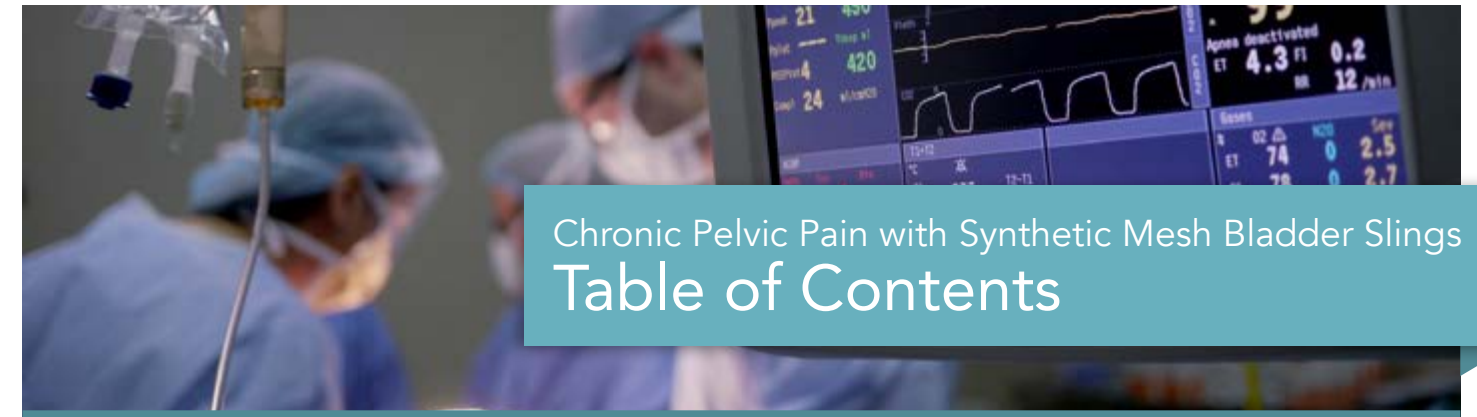
with Synthetic Mesh Bladder Slings

Featuring:

Michael C. Hibner, MD

Director: Arizona Center for Pelvic Pain

St. Joseph's Hospital and Medical Center, Phoenix



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Chronic Pelvic Pain with Synthetic Mesh Bladder Slings

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Chronic pelvic pain occurs frequently among women who have been treated for (POP) pelvic organ prolapse or (SUI) stress urinary incontinence with the implantation of synthetic mesh bladder slings.

Dr. Michael Hibner explains this debilitating condition is commonly unrecognized.

“Pain is one of the most common complaints that gynecological patients have. For many years this was not necessarily recognized by the gynecological community. Gynecologists or gynecological surgeons were there to treat all the problems other than pain. Women that were presenting with pain were considered complainers or fakers. I think our practice, probably more than many

Patients who suffer from serious adverse events should not wait but need to seek timely and specialized medical treatment.

other practices, helped change that.”

Health complications including pain that occur secondary to the implantation of a synthetic mesh bladder sling often require surgical intervention and ongoing therapies. Patients who suffer from serious adverse events should not wait but need to seek timely and specialized medical treatment.

“In patients who have developed symptoms after placement of mesh, it is very important to get to a right provider. The longer they wait, the more severe their pain gets. With every day, it becomes more and more difficult to treat them.”

Women Deserve Their Day in Court

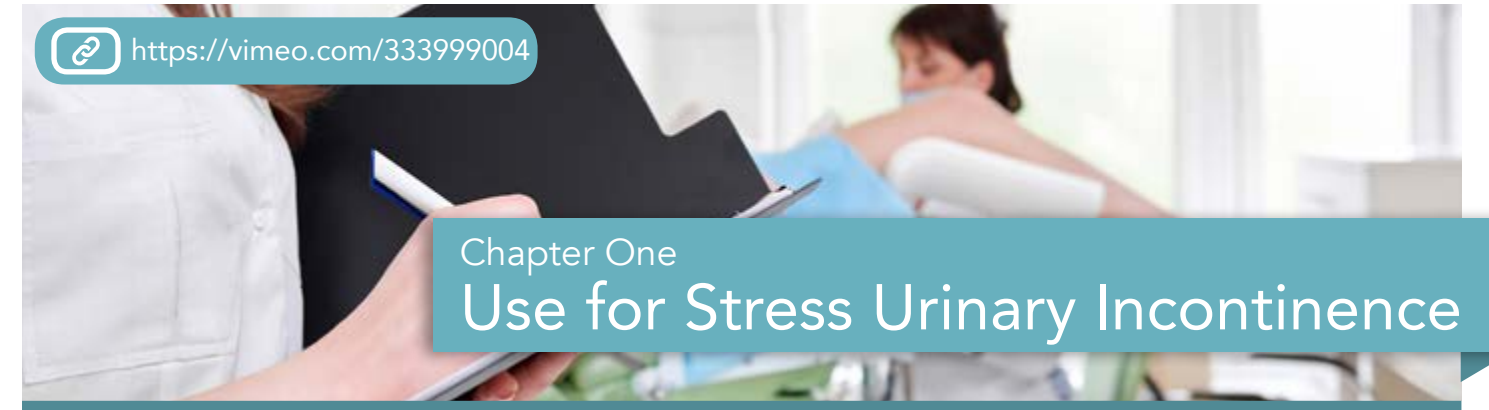
In addition to receiving expert medical care, women with neuromuscular complications from transvaginal mesh devices can pursue a case in court against the manufacturers where they can be held responsible and required to pay damages.

Dr. Greg Vigna is a practicing physician, attorney, and certified life care planner. Working with a team of top trial lawyers with outstanding national reputations, Dr. Vigna is committed to providing his clients with exceptional legal representation.

“Clients who come to me are financially destroyed from catastrophic injuries. They deserve their day in court which is the path to financial compensation for their injuries caused by these defective and dangerous medical devices.”

Greg Vigna, MD, JD

Board Certified Physical Medicine and Rehabilitation
 Certified Life Care Planner
 Attorney, California and Washington, D.C.



Historically, surgeons have used synthetic meshes to treat hernias. Over the past 15 years, mesh devices were developed and implanted in women for the treatment of pelvic organ prolapse and stress urinary incontinence.

Mesh Bladder Sling Implantation

One of these mesh devices is a synthetic bladder sling which is made of polypropylene. It is positioned under the urethra and has arms which are attached to nearby pelvic muscles and fascicle tissue. Several surgical methods have been utilized to perform the implantation.

Mesh Bladder Sling Surgical Approaches

The most common surgical procedure is the transobturator approach.

“The mesh we see very often in our practice causing complications is the transobturator sling. It pierces through the obturator internus muscle and other muscles in the groin. A lot of these patients have problems with ambulation.”

Additionally, there is the retropubic approach.

“The retropubic sling is attached behind the pubic bone and perforates through part of the levator muscle. These women are probably more mobile but the pain may still be debilitating with symptoms that are equally severe. I’m not just talking about pain with intercourse. They have pain with urination, pain with bowel movement and they have difficulty emptying their bladder. They may not be able to urinate at all. So the disability is very severe.”

Mesh Mini-Sling Introduction

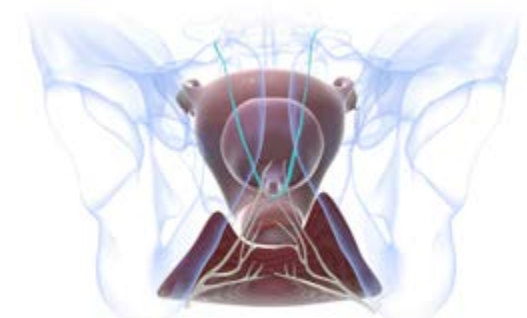
More recently, mini-bladder slings were introduced to the market, which eliminated the need upon implantation to perforate pelvic muscles. However, health complications were still occurring which included chronic pain.

“There are definitely patients that still show up with that type of sling. It is true that those mini-slings do not pierce through all the muscles that the older types do, but they still attach somehow to the obturator membrane in order to stay in place. Yes, the pain from mini-slings may be as debilitating.”

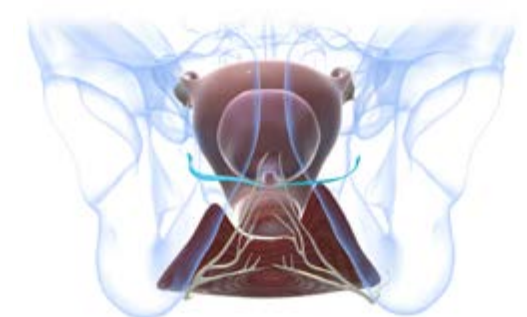
Surgical Approaches



Transobturator



Retropubic



Mini Sling



<https://vimeo.com/333999568>

Chapter Two Associated Health Complications

Over the years, thousands of cases involving health complications have been reported following the implantation of synthetic mesh including the bladder sling. Those complications include pelvic muscle spasms and pain, nerve pain, infection, bleeding, pain during sex, organ perforation and urinary problems.

FDA Action

In 2011, the FDA re-classified this synthetic mesh from moderate to a high-risk medical device for the treatment of pelvic organ prolapse.

Health Complications Now or Later

Unfortunately, most of these mesh devices were designed to be embedded in the muscle tissues that are adjacent to vital nerves which are responsible for mobility, sexual function, and bowel and bladder function. Symptoms of adverse events caused by synthetic mesh sling implantation can occur immediately after surgery or years later.

Mesh Shrinkage

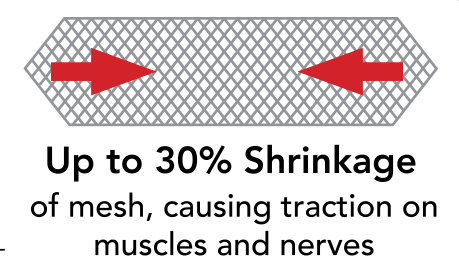
When implanted, the devices cause scar tissue. Over time, studies show that the mesh can shrink up to 30%, leading to traction on adjacent structures including muscles and nerves, causing muscle and nerve pain. Particularly impacted by the mesh shrinkage are the clitoral nerve, the rectal nerve, the pudendal nerve and the obturator nerve.

"Not all women develop pain immediately after mesh and that is perfectly explainable because the mesh shrinks. You will see that maybe it doesn't pull on the muscle immediately after the placement. It may pull on it a few years later."

RE-CLASSIFICATION



Synthetic Mesh Bladder Sling
Moderate → High Risk



Painful Bladder Syndrome

Health problems following mesh implantation include a worsening of urinary incontinence. In some cases, mesh failure causes Interstitial Cystitis which is painful bladder.

"Normally, the bladder should only hurt when it's really full. An allodynia is when the slightest sensation to the bladder causes pain. It most likely originates from some other painful condition somewhere else in the pelvis where a muscle spasm happens. With a muscle spasm, the patients develop obstructive voiding. The muscles don't relax enough for patients to empty the bladder. When you have a patient with mesh that causes muscle spasm, then it may lead to painful bladder syndrome."

Painful Bladder Treatment

Often, treatment of Interstitial Cystitis involves hydrodistention, which is filling the bladder with a saline solution.

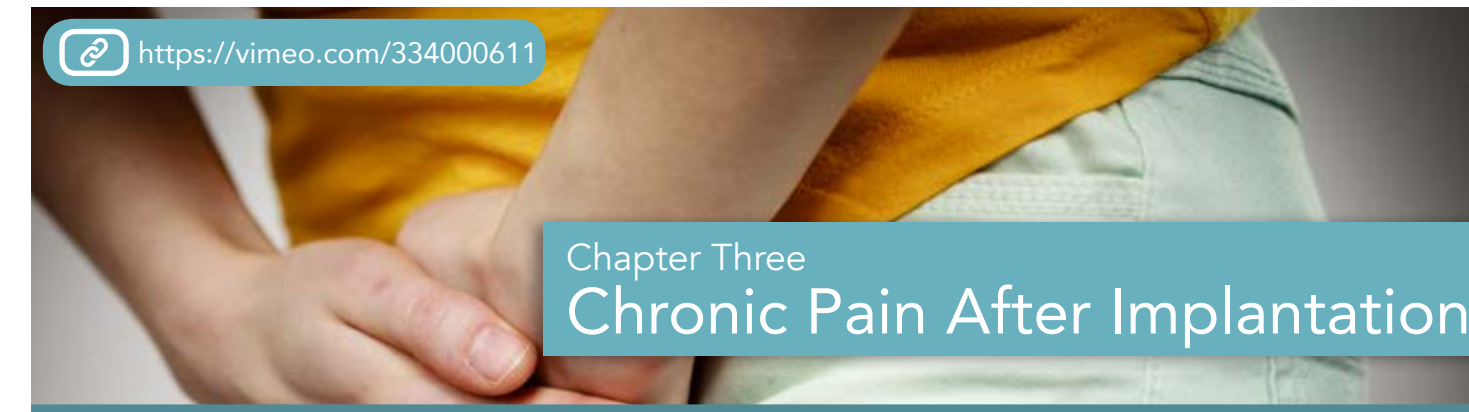
"The hydrodistention actually helps with symptoms, but it is helping temporarily. It is like you have pain for muscle spasm and you take a muscle relaxer and it's not really curing your muscle spasm. So that's kind of what hydrodistention is. I think it is still an important procedure but it's not going to cure that patient's pain unless the mesh comes out."

Bowel and Bladder Erosion

Failure of a mesh device can lead to erosion of the bowel and bladder, severely disrupting their function.

"It definitely is a significant problem because it may cause leakage of the contents of the bowel or the bladder into the abdominal cavity. It may cause peri-

tonitis. It also by itself is very painful. It requires a very complicated surgery to repair it and to close the defect. It is a significant surgical problem."



<https://vimeo.com/334000611>

Chapter Three Chronic Pain After Implantation

Significant chronic pelvic pain is a predictable health complication for these women. Extreme discomfort can be experienced just by touch to the labia or anus. Muscle spasms are a common source of pain and include pelvic floor spasms or obturator muscle spasms. These spasms are often excruciating to the sufferer.

Pelvic Floor Muscle Spasms

Implanted in the levator muscle, retropubic slings can cause pelvic floor muscle spasms that interfere with daily activities. In the case of the transobturator sling where it is implanted in the obturator internus muscle, painful spasms can also inhibit mobility, often significantly.

"In cases of the obturator internus muscle, when that muscle spasms it hurts with movement of the lower extremities, it hurts with walking. It hurts with pretty much everything that's involved with lower extremities."

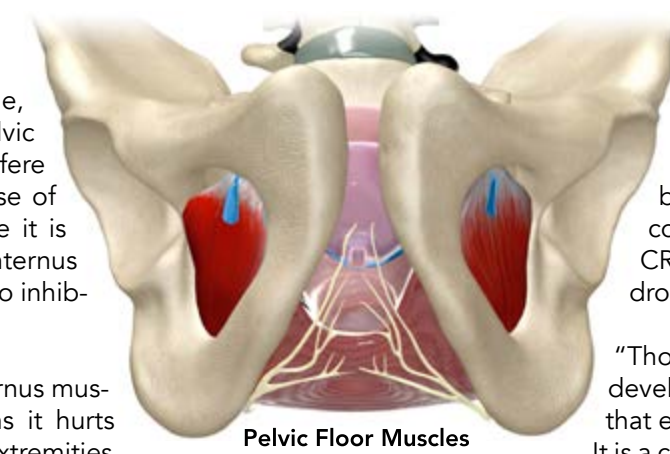
Chronic Neuralgia or Nerve Pain

Along with muscle pain, there can be neuralgia or nerve pain which is sharp, intense and occurs spontaneously. In the pelvis, neuralgias can involve the obturator or pudendal nerve, specifically in its lower branch, the dorsal clitoral nerve.

"We see that not only with the obturator nerve but with other nerves where the initial pain starts as a muscle spasm. When this muscle spasms around the nerve, the pain will then start in the nerve itself. Then patients will have pain both in the muscle and in the nerve."

Symptoms of Pudendal and Obturator Neuralgia

With pudendal neuralgia or obturator neuralgia, women can experience pain by simply sitting, a burning with urination or pain with bowel movement. Also, pain may occur during sexual arousal, intercourse and orgasm.



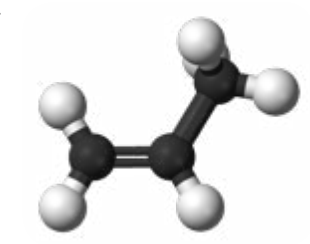
Complex Regional Pain Syndrome

If left unchecked and untreated, chronic pelvic pain can develop beyond specific areas, becoming compartmentalized. It is known as CRPS or Complex Regional Pain Syndrome.

"Those are the patients that over time develop centralized pain. I mean pain that exists in the central nervous system. It is a condition where you may completely treat the pain in the pelvis, but it is still present in the nervous system. Any type of injury to the pelvis, including mesh, may cause that pain."

Reaction to Foreign Bodies

Additionally, centralization of pain can be caused by the individual's response to the presence of foreign bodies, meaning the synthetic mesh itself.



"With muscle spasm, there is ischemia which is decreased blood flow to the area. On top of that, there is a foreign body reaction and probably reaction to the actual chemical of polypropylene itself. This may lead to development of complex regional pain syndrome or centralization of pain in the central nervous system."



<https://vimeo.com/334001338>

Chapter Four Choosing the Right Health Care Provider for Treatment

With symptoms of chronic pelvic pain associated with the use of synthetic mesh bladder slings, women need to seek expert medical evaluation, may undergo potential surgeries, and must receive effective pain treatment.

Visit to a Chronic Pain Treatment Center

Dr. Hibner outlines what a new patient can expect upon arrival for an evaluation at their specialized pain center. It involves radiological imaging and an examination by a team of health care providers including a physical therapist and treating physicians.

"We review their records, especially if this is a mesh patient who had mesh placement previously and then had mesh removals. We carefully analyze what mesh was placed and what mesh was taken out. And then after we discuss the case, I see the patient with all this information. And then I come up with a solution for her."



Arizona Center for Pelvic Pain
St. Joseph's Medical Center Phoenix



<https://vimeo.com/334001993>

Chapter Five Treatment Protocols for Health Complications

Women suffering from chronic pelvic pain associated with synthetic mesh implantation need an individual treatment plan based on their specific circumstances.

"Each patient is treated individually depending on what reason there was for the pain or what happened when the pain started. It's not only about removing mesh. It is to take care of all the other reasons that

surround the pain in patients with mesh like CRPS, like nerve injury or muscle spasm."

Treatment Protocols for Health Complications

Following the initial in-depth medical evaluation, established treatment protocols for bladder sling health complications involve prescribed pain therapies, and then when indicated, revision surgery,

re-constructive surgery, continued chronic pain treatment and psychological support for depression.

Dr. Hibner emphasizes that in revision surgery all of the mesh needs to be removed which commonly in previous procedures may not have been accomplished.

"When I see the patient with mesh injury, I do believe that the mesh needs to be removed completely and that's for basically two reasons. Number one, you can't really tell which part of the mesh is causing pain which most likely are the arms of the mesh, not the vaginal part of the mesh. Secondly, if you remove parts of the mesh, the rest of it may be very difficult to find. It is much easier to remove the entire mesh in one piece rather than removing it partially and then going back in and trying to find whatever was left behind."

Continuation of Prolapse or Incontinence

Following mesh removal, if there is a re-occurrence or continuation of pelvic organ prolapse or stress urinary incontinence, a traditional non-mesh re-con-

structive procedure might be indicated.

"We do other surgeries than mesh removals. For patients who had mesh removal and (still) have urinary incontinence, we work with your urogynecologist who will perform re-constructive surgery. Those procedures are generally done with the patients' own tissues and fascia or sutures without using synthetic mesh."

Treatment Protocols

- Radiological Images: CT Scan
- Evaluation of Medical Record
- Medical Team Review
- Prescribed Therapies
- Revision Surgery with Complete Removal
- Reconstructive Surgery for Continued Incontinence
- Ongoing Chronic Pain Treatment

Pain Treatment

- Physical Therapy
- Botox Injections
- Vaginal Suppositories with Valium, Ketamine or Baclofen
- Nerve Blocks

Pain Therapies After Surgery

For continued pelvic pain following surgery, specific therapies to treat muscle and nerve pain are initiated or continued which include physical therapy, Botox injections, vaginal suppositories with Valium, Ketamine and/or Baclofen. And if needed, targeted nerve blocks can be performed with anesthetics and steroids.

"Most of the patients who had removal of the transobturator sling are very happy with their results. However, they may still require physical therapy. They may still require muscle relaxants or Botox injections. There are not many patients that do not require any treatments."



<https://vimeo.com/334002731>

Chapter Six Ongoing Pain Therapies and Procedures with Complications

Ongoing treatments of chronic pelvic pain caused by the use of mesh slings include physical therapy, opioid pain medications, Gabapentin, for weakness, numbness and chronic pain from nerve damage, antidepressants, muscle relaxers including Baclofen and Valium suppositories, Botox to the pelvic floor and Ketamine suppositories or ointments.

"The treatment for centralized pain is nerve blocks and ketamine from vaginal suppositories that we use very commonly. Ketamine works on the central nervous system. Those patients also have pain from

muscle spasms and it creates a positive feedback loop. They have pain that causes muscle spasm, which causes more pain. So you need to break that positive feedback loop. You do that with Botox. You try to relax the muscles. Then you do physical therapy because it is what retrains the muscles. It is what makes the Botox more permanent. And when patients start understanding that there's no magic treatment that it takes time and years of work from them, then they start to understand that they will get better."

Nerve Decompression or Cryoablation Procedures

In some cases, to treat continued neuralgia or nerve pain, a nerve decompression can be indicated which relieves pressure on the nerve. Or a cryoablation is performed which uses extreme cold to destroy the nerve eliminating the source of the pain.

"If their pain continues, one of the treatment modalities would be to do either cryoablation or a pulse radio frequency ablation on one of the nerves that may be responsible for their pain. We determine which nerve to use the cryoablation by doing selective nerve blocks. We have developed a way of blocking every sensory nerve in the pelvis where we can selectively block them at different times to narrow down the diag-

Ongoing Pain Treatment

- Physical Therapy
- Opioid Pain Medications
- Gabapentin
- Antidepressants
- Muscle Relaxers : Baclofen/Valium Suppositories
- Botox Injections
- Ketamine Suppositories for Neuropathic Pain
- Nerve Decompression
- Cryoablation: Destruction of Painful Nerve Endings
- Spinal Cord Stimulator

nosis, which nerve is responsible for the pain. Once we know, we can actually destroy that nerve with cryoablation."

Spinal Cord Stimulation

Additionally, if pain persists, use of a spinal cord stimulator might be indicated which is a type of implantable neuro-modulation device that is used to send electrical signals to select areas of the spinal cord.

"Spinal cord stimulator is the procedure that is good for the patients where everything else has failed. It is usually done by pain anesthesiologists. They place leads into the spinal cord and to the area that has pain centers. They're able to send electrical signals to those areas and regulate the pain impulses that go into the central nervous system."

<https://vimeo.com/334004374>

Chapter Seven Associated Depression and Family Stresses

Families can be profoundly impacted by a woman's health problems associated with the use of synthetic meshes in the treatment of pelvic organ prolapse and stress urinary incontinence. These women endure debilitating pain and ongoing physical disabilities. With their spouses, they share the loss of an intimate physical relationship.

"Several years ago we did a study in our practice on the quality of life of patients with catastrophic pain. We obtained quality of life scores and compared the quality of life of patients with mesh pain to quality of life of patients with other significant diseases or disabilities. Patients that have catastrophic pain from mesh have a lower quality of life than someone who has double lower extremity amputation or lung cancer."

Need for Psychological Support

For these women, chronic pelvic pain and physical

dysfunction caused by a failed synthetic mesh bladder sling often leads to severe depression and requires psychological support and counseling.

"Unfortunately we see a very high rate of depression among our patients. Those are women who are in chronic and debilitating pain. They may have lost their job because they can't work. They may have lost their partner because they're not able to be sexually active. So, of course they're very depressed. We unfortunately every now and then have patients that may be attempting suicide and that's very difficult for all of us."

Improved Quality of Life

With proper care and treatment for women with mesh related problems, physical and psychological, their health can improve and their quality of life can be potentially restored.



