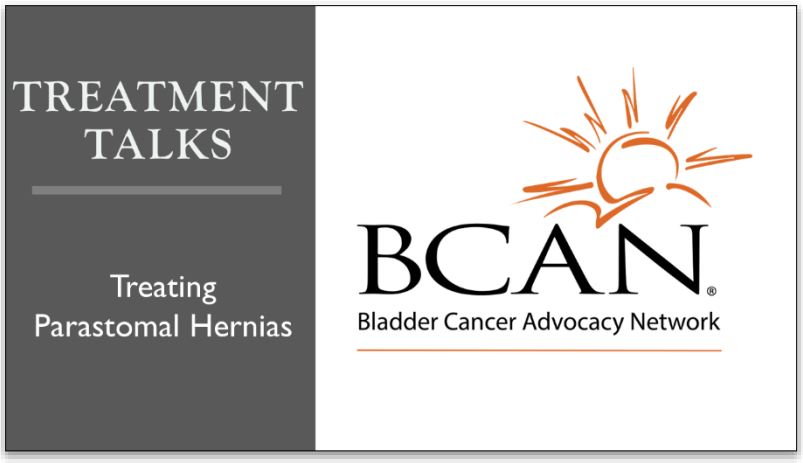


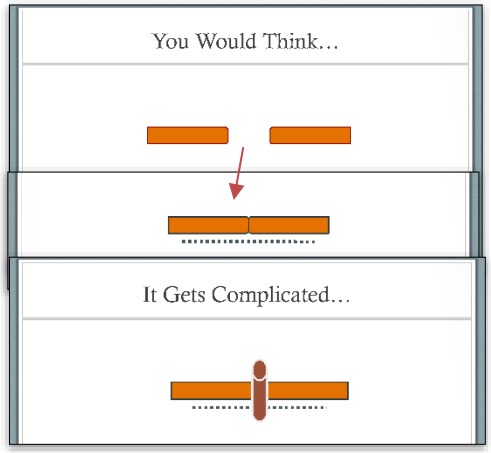
Morgan Stout:

Parastomal hernias are common problem for about 50% of patients that have a stoma after a radical cystectomy. A parastomal hernia is when intestines protrude through the abdominal wall at the side of the stoma. My name is Morgan Stout, and I'm the Outreach and Education Manager here at the Bladder Cancer Advocacy Network. Today, I am joined by Dr. Benjamin Poulose, from the Ohio State University and patient advocate, Darrell, from Chicago. Welcome. First, Dr. Poulose will talk about parastomal hernia, what it is and how it's treated. And then I will hand it over to Darrell, to talk about the lived experience of having a parastomal hernia. So with that, Dr. Poulose, I will hand it over to you.

Dr. Poulose:

Hi, thanks everybody. I really appreciate the opportunity to chat with you this evening, and I'm looking forward to a very robust discussion and it should be a really fun one. So I'm going to share my screen here. Thanks again. And as Morgan mentioned, I'm one of the faculty here at Ohio State, and my practice is largely in hernias and also specifically parastomal hernias. And these are some of my disclosures. I do receive salary support from our quality collaborative, which collects data around hernias in general. And I also receive research support from the following institutions. And I also have a startup company listed there, that's unrelated to the content I'm talking about here. A little bit about myself. So I actually was born in Southern India in a very tropical climate, and it was a beautiful area. My parents left for the opportunities here in the United States and we moved to Brooklyn, New York. And from there, my parents followed the jobs and we ended up from Brooklyn, New York, in love with North Kansas, which is where I grew up. So I definitely grew up in the Midwest, went to school as an undergraduate at UNC Chapel Hill. And then I did my medical school at John's Hopkins Hospital in Baltimore. Left there and did my surgical training at Vanderbilt University, went to Ohio for my specialization in minimally invasive surgery and abdominal wall reconstruction. Back to Vanderbilt as faculty for 10 years there, and I founded the Vanderbilt Hernia Center. And then apparently, all roads lead back to Ohio, so back to Ohio for a job and have been here at Ohio State now for the past four years and it's been a ton of fun.

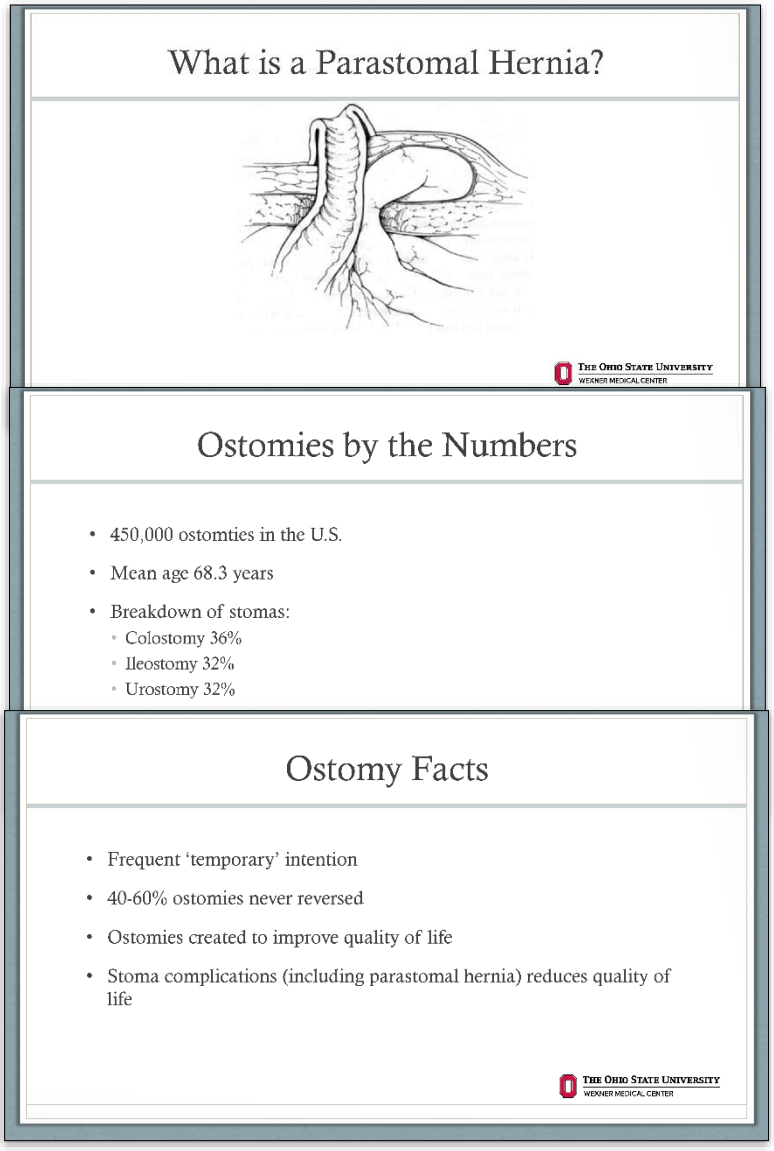
Dr. Poulose:



So you would think that we would have the ability to take a hole in the anterior abdominal wall or core musculature, and close it maybe with some type of mesh and people do okay.

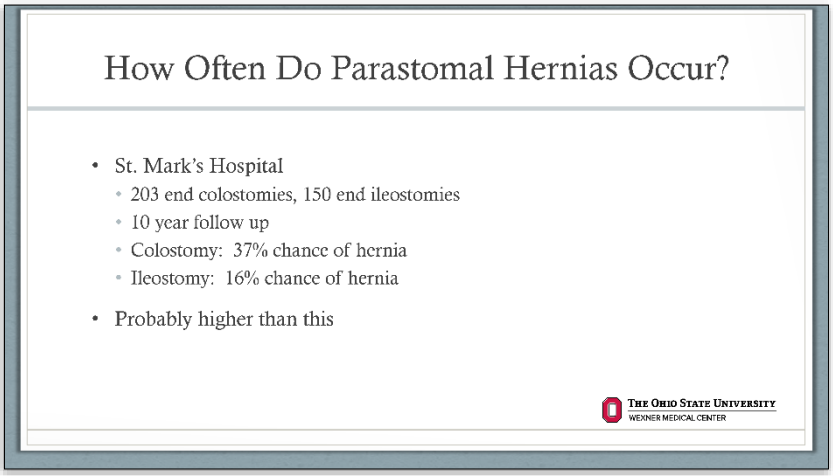
Well, it gets complicated, because even that simple process can be very, very challenging to keep that hole closed over time. It gets even more complicated when you have to have a control hole, if you will, when you have an ostomy of any sort, be it a urostomy, a colostomy, or an ileostomy, where you have to keep that hole just wide enough to allow it to pass through, not too big and not too small. So these are the topics I'm going to cover today.

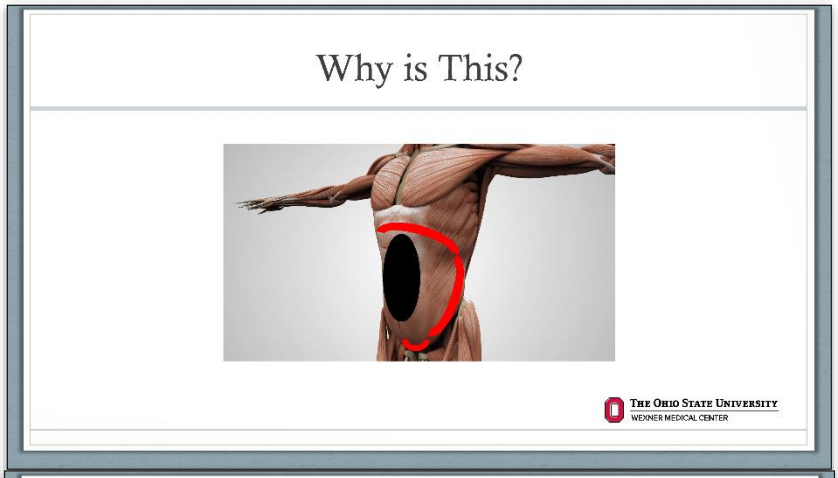
What is a parastomal hernia? Why do they happen? How do we treat parastomal hernias? And I also have some discussion time at the end to chat, I'm sure you'll have a lot of questions. So what is a parastomal hernia? So as mentioned, a stoma itself is kind of a controlled hernia, where you have to have a hole in the abdominal core musculature, to allow the ostomy to pass through. But a parastomal hernia is, alongside that hole, you have something else passing through, and typically it's a piece of small intestine or even colon, that can pass through and get stuck in between the abdominal wall and also where the ostomy is. And this can lead to several symptoms. Sometimes it can be completely asymptomatic and not have any symptoms associated with it. Other times you can have pain, even blockages from it, that can result in some serious consequences potentially. So looking at ostomies overall, about just under half a million ostomies are created in the US alone, with the mean age there. And if you look at the different type of stomas that you can have, colostomies really are the majority, but also ileostomies and urostomies are fairly common as well. So some facts about ostomies, oftentimes their intention, intended to be temporary type of things. But however, over 40 to 60% of ostomies actually are never reversed, and they're there for life.

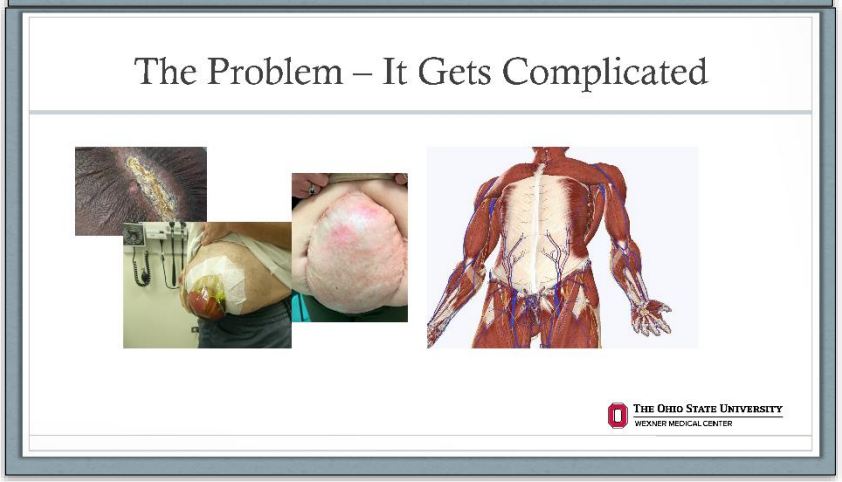


Dr. Poulose:

Ostomies in general are created to improve quality of life, oftentimes due to a life saving cancer operation that can result in an ostomy, basically diverting either food or urine away from where the cancer was. Stoma complications, including parastomal hernia, certainly can reduce quality of life. And that's something we'll spend a fair amount of time talking about here. So how often do these occur, parastomal hernias? In one study... this is done at a colorectal hospital in England, 203 end colostomies and 150 end ileostomies were evaluated over a long time. And if you look at over this timeframe, ostomy is formed anywhere from 16 to 37% of the time, and it's probably higher than this. A very famous colorectal surgeon, Dr. Gathright, once mentioned, "If you have an ostomy long enough, you have a 100% risk of parastomal hernia." Well, why is this? And we think we're just beginning to understand why this is the case. If you think about the torso, not necessarily as how we traditionally think about the abdomen organs inside it, but more as a functional unit of the core muscles, where there's a pelvic floor, the back and the diaphragm and of course the anterior abdominal wall. If you have a hole in the anterior abdominal wall, either a hernia or an ostomy, which again is a controlled hernia, it's a natural weakness that can lead to hernias forming around the valve where the stoma is.



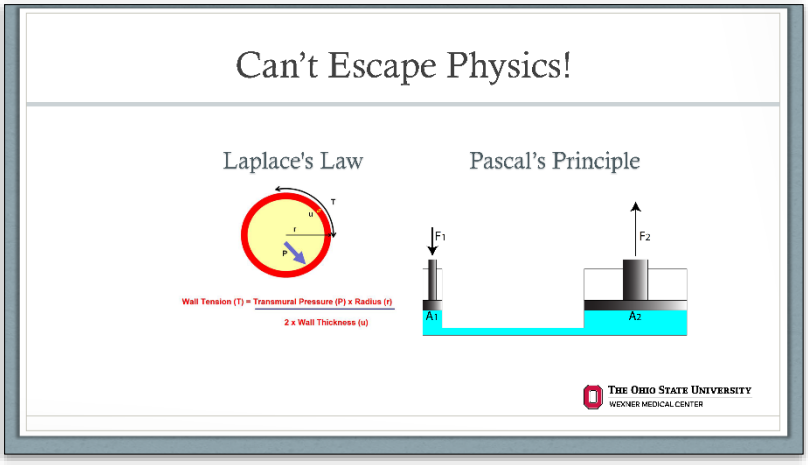


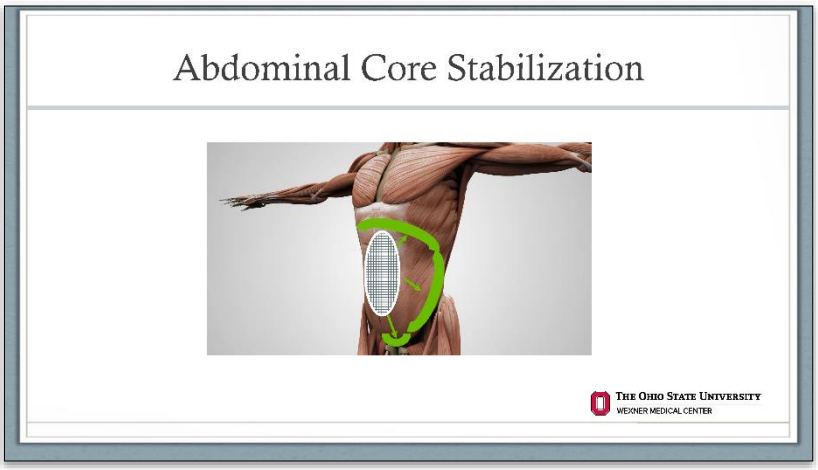


Dr. Poulose:

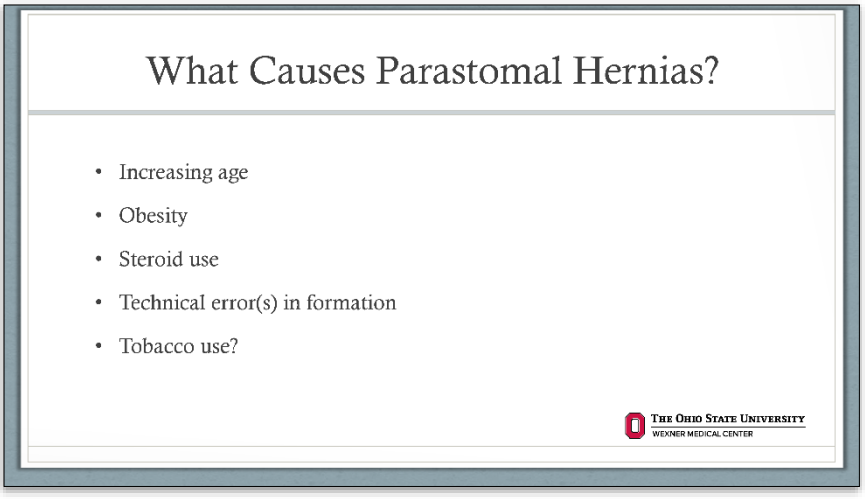
So it gets complicated as mentioned, also because as a field, we think that physicians and surgeons have really underestimated the complexity of the anterior abdominal wall. And it becomes hard, because especially when you think about why ostomies are created to treat cancers, I mean, that's complex enough. And for other reasons, let alone trying to think

about how to prevent a hernia from forming. But we do know it's very similarly complex just to treat these hernias and sometimes even more complex to prevent these hernias from happening in the first place. And hate to bring this up, this may bring up some PTSD from high school or even college in terms of physics, we can't escape physics. There are two laws that are at play here, Laplace's law, which describes wall tension on across a cylinder. And also Pascal's principle, which tells us that force of flow applied in a fluid system, is then applied to every area in that fluid system. Those two concepts are really critical, because our trunk or our core muscles is basically a big cylinder that has to obey those laws. And so, there's a baseline pressure inside our abdominal cavities that is constantly pushing things out. And you can imagine if there's a hole anywhere in that cylinder or the core, it's a natural, weak spot that allows things to protrude through. Now, repairing that core muscles or those core muscles, be it with a hernia repair or other means, we are learning that you can actually stabilize the abdominal core and treat those hernias. Ostomies though, we can't completely stabilize the abdominal core musculature for that main reason as we mentioned, that it's kind of a controlled hernia with a natural, weak spot there. And this is why we think that hernias form at some point over the course of having the ostomy for years.



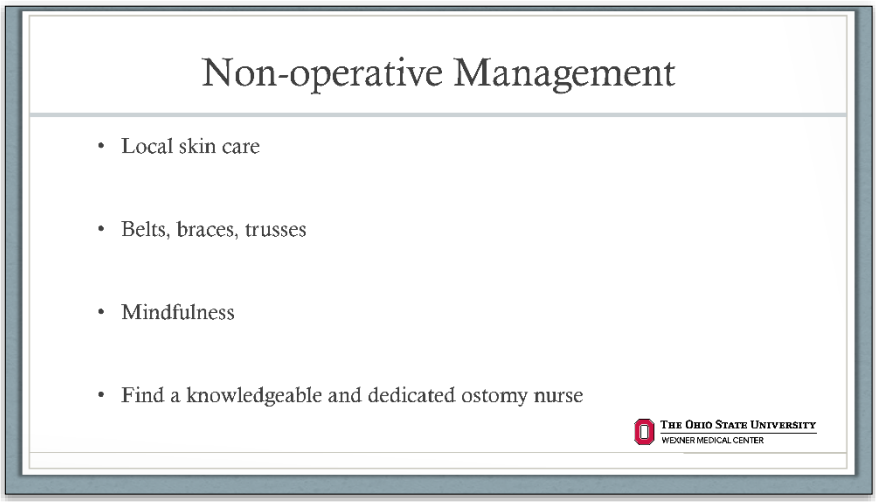


So what causes parastomal hernias? Certainly there are some risk factors, including increasing age, obesity, steroid use, sometimes technical errors when you create the ostomy can lead to hernias forming. And we also think that tobacco use, may play a role in it from a wound healing standpoint, although that's not very well thought to be contributing to the hernias forming in the first place. The biggest factor really, is it just happens, for the reasons I mentioned in terms of that interplay between pressures and core muscles and you have a controlled hernia, it just happens over time because we live our life and we have a baseline pressure in our abdominal cavity, it tends to push things out through holes there. So how and why do we treat parastomal hernias? I'm going to go a little bit over non-



operative management, which is really key for managing symptoms associated with the parastomal hernias, and we'll talk a little bit about surgery.

Dr. Poulose:



Non-operative management is really, really important. And this is really important because if you think about what I just said and what the information I presented, that if you wait long enough, you're going to have a hernia associated with an ostomy. Well, if that's true, then you have to think, you have to have an ability to manage yourself as a patient over time with unfortunately, some component of a hernia. Now, a lot of times they don't cause any symptoms and so then you would think that the threshold of recommending repair, would not be met. Because if it doesn't cause many symptoms although you have a hernia, although it's not an ideal situation, it's somewhat of a controlled situation that most people learn how to live with. And these are the mainstays of learning how to live with a parastomal hernia. Certainly local skincare is really important, especially if you're having difficulty placing a pouch over the ostomy, because of the hernia itself. You of course want to minimize spillage, leakage and you can sometimes use different types of adhesives and different barriers to help manage that. Belts, braces and trusses can help to some degree. The only problem with this is, sometimes it's very difficult to fit something that adequately holds enough pressure to kind of keep the hernia at bay, if you will. And I added mindfulness here, not so much to kind of be cute about it. It's really an important point, because if you're coming to me or another abdominal core specialist with a parastomal hernia, oftentimes our recommendation especially at the early onset of it, if it's not causing a lot of symptoms, is just to wait, and to deal with some of the issues that you may face with having a parastomal hernia.

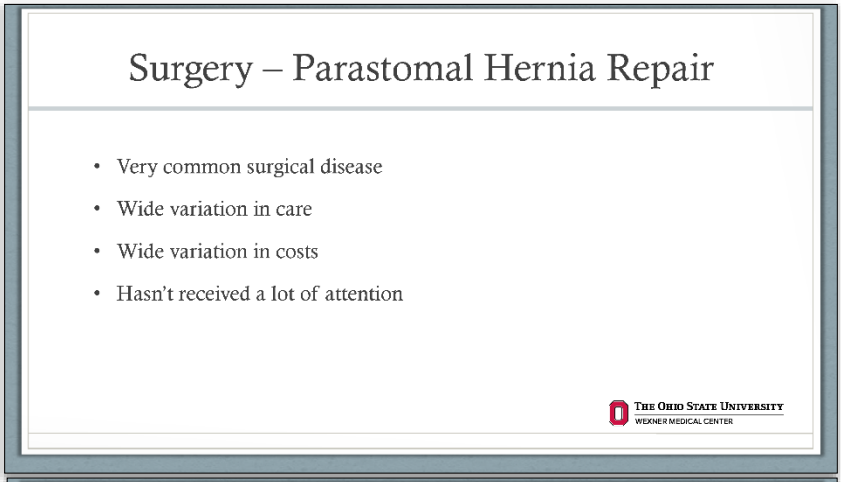
And the reason why this is important, is because we're trying to stretch out as much time as possible between doing surgery, knowing that even after you repair it, there's a very, very high chance of it coming back. And this sometimes becomes a mind game, especially if you've had a history of cancer. Because one thing that I've found is that, most of us who have problems like that, and most of you who've had cancers treated, you're very much in the mindset of, well, we want to take care of things right now, and attack these cancers, and attack these parastomal hernias and fix them. And sometimes, that's a little bit difficult to apply to these parastomal hernias, so it's really a change in mindset that's different than what a lot of folks are used to dealing with. And that's important, because I think some acceptance of having the parastomal hernia, knowing it's not going to be fixed for a while, is an important way to manage these hernias themselves.

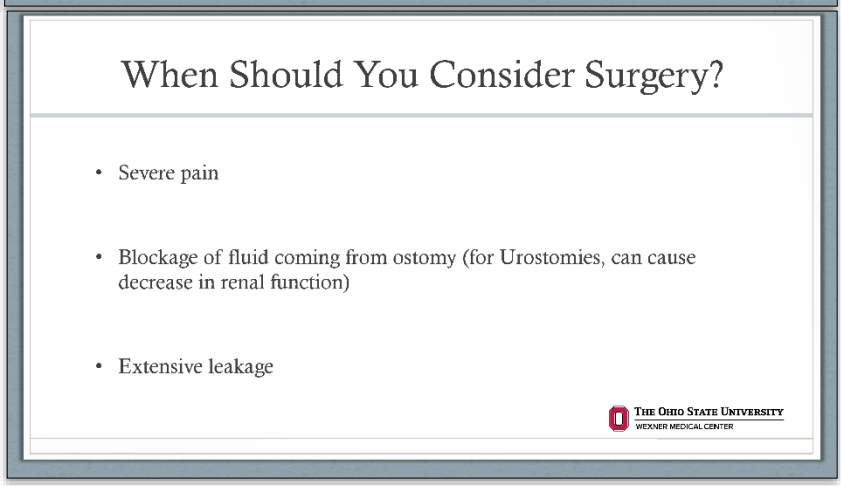
Dr. Poulose:

I think one thing that's really key, is finding a knowledgeable and dedicated ostomy nurse, because they have a number of tricks available to them, to making your life easier to live with the parastomal hernia, that can oftentimes end up having the parastomal hernia for years and not necessarily having surgery. This is a patient of mine who had a cystectomy about three years ago, presented to me with a

parastomal hernia, you can see there. And he tried to use an abdominal binder to a reasonable degree, and used the binder for about three years. And then the hernia just kept protruding more and more to the point where the binder was not very helpful. He was having a lot of pain from the parastomal hernia and more importantly, he and myself and the urologist thought that the hernia itself, was causing some obstruction of his urinary tract causing to have some decreased renal function. And so I'll tell you his outcome later on in the talk, and we went ahead and repaired it for those reasons. And I think that's an important example of the threshold we would use for deciding to recommend surgery or not.

So parastomal hernia repair, again, it's a very common surgical disease and wide variation care is obtained. I'm going to change my talk here for one second, here we go. And so, our goal with parastomal hernia repair is to take this hernia here itself, that's adjacent to the bowel coming through the ostomy, and fix it. And either put a piece of mesh below it or a piece of mesh on top of it, and then have things heal up and you should be okay. So when should you consider this kind of surgery? As mentioned before, when you have severe pain, when you have blockage of fluid coming from the ostomy, and as mentioned for urostomy, this can cause a decrease in renal function.

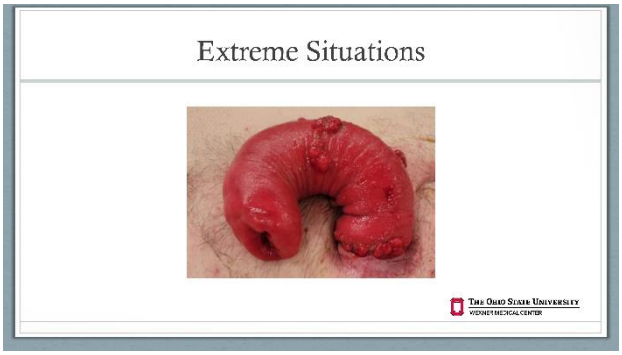




Dr. Poulose:

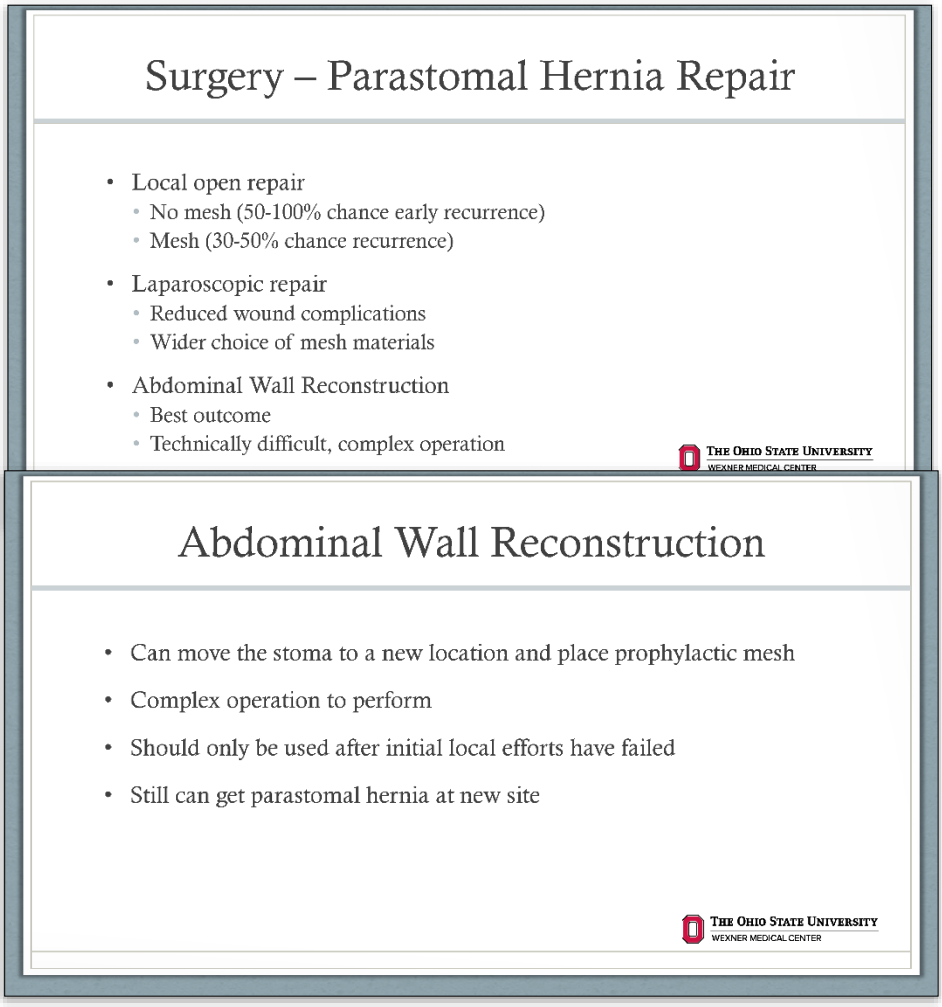
And also, when you have extensive leakage that cannot be controlled by any recommendations that our ostomy nurses have, and especially if you're having leakage on a daily basis that's just making your life miserable, those would be pretty clear indications to go ahead and do the repair. In extreme situations also, we recommend repair.

This is a patient who had an ileostomy and actually had parastomal hernia, but also had a prolapse of the ileostomy. The bowel was just kind of pushing through the middle there, leading to a very unstable and difficult situation for which we performed a repair.



Dr. Poulose:

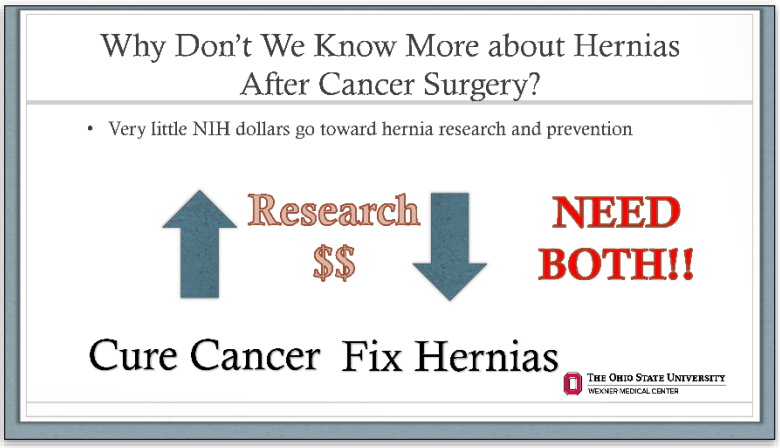
So if you look at the common types of parastomal hernia repair, they really break down in three different categories. One is what's called a local open repair, where we make an incision somewhere around the stoma itself. We do know that if you don't use mesh, there's a very high chance of early recurrence of these ostomy hernias. If you use mesh, it does decrease the chance of recurrence. And it does vary the time to recurrence, which is often very, very variable. The laparoscopic repair, and also it's now done robotically, can reduce wound complications, it does afford you a wider choice of mesh materials. The problem with the laparoscopic or even a robotic repair, is that we can only tend to place the mesh inside the abdominal cavity, and that has some consequences for later on, trying to repair a recurrence of the hernia or other surgery you might have. Abdominal wall reconstruction is a more complex, technically difficult operation, where we would do very complex maneuvers to the muscle and the what are called the fascial coverings of the muscle around where the hernia is. And sometimes we may actually recommend moving the ostomy to a different spot, to then start with the fresh site.



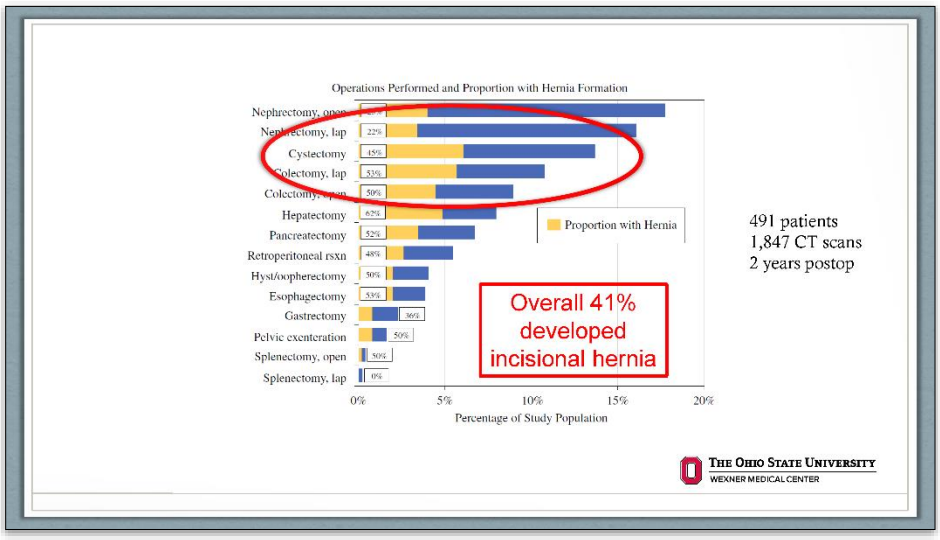
Dr. Poulose:

And that is an advantage of this more formal and extensive abdominal wall reconstruction, sometimes we can even place prophylactic mesh at the new site, to help extend the time without having a hernia at that site. However, it is a complex operation to perform, and this should only be used after initial local efforts that repairs have failed. And certainly, unfortunately you can still get a new parastomal hernia at the new site there as well.

Dr. Poulose:



So why don't we know more about hernias after cancer surgery? And this is an important point to make, especially for groups like yours. Unfortunately, there's very little dollars, federal funding dollars that go towards hernia research and prevention. And if you think about this, it kind of makes sense at face value, you have to choose between curing cancer and fixing hernias. I think most people would agree that curing cancer is probably more important. Where it becomes a little more complicated, is after we cure the cancer, and now you have a hernia impacting your quality of life and your cancer survivorship. We do need some additional information to help us figure out what to do. Obviously, we need both. We need investments both in curing cancer, but also, in making sure your life as a cancer-free patient, is of high quality and you're not dealing with a lot of consequences from oftentimes a curative recession of cancer, but now that's impacting your quality of life. We did a study a few years back looking at cancer survivorship, and we just wanted to see what's the chance of developing any kind of hernia in your core muscles after having life saving cancer surgery for an intra-abdominal cancer.

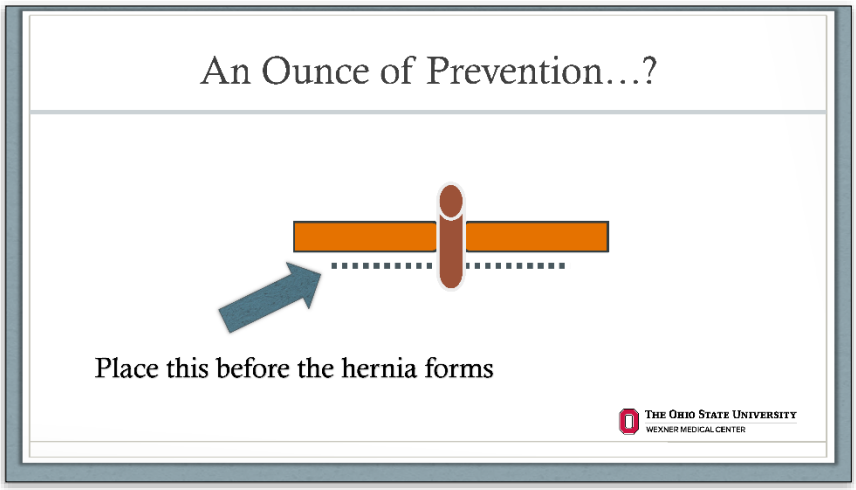


Well, if you look at the information we found, it was actually fascinating. In this graph, we show different operations on the left, and on the bottom, you see the percentage of the study population that developed a hernia. The yellow bars show the percentage of patients with the hernia for each one of those operations.

Dr. Poulose:

And what we found is that overall, amazingly enough, 41%, just less than half, developed a hernia within two years of their life saving cancer operation. Specifically to this group after cystectomy, it was even higher than that. About 45% of patients in two years developed some type of hernia, most of these were in fact parastomal hernias. So the other kind of compelling discussion that's increased in its focus is, what about the time of the creation of the ostomy, can you help reduce the chance of the hernia forming, for instance, by placing mesh prophylactically in the area to reinforce that?

Dr. Poulose:



We are finding that there is some information to show us that this actually may have some benefit in at least delaying the formation of parastomal hernias, but it's very, very in its early stages. And one of the trade offs is, now you have to place... you're using mesh at the time of an initial operation, which has its own consequences, but our initial results are that, it does have some advantage however, the jury's not quite out yet on the effectiveness of this. So in summary, we've gone over what a parastomal hernia is. We talked a little bit about why they happen specifically in terms of this pressure in the core muscles there. And we talked a little bit also about treating parastomals, learning that the non-operative management with local skincare, meshes, binders, hernia belts, and finding a really experienced and invested awesome nurse, really can extend the time of having a parastomal hernia, but not so much where it impacts your quality of life negatively. And then of course, we'll transition now to talking about our patient experiences. I want to hear from you in terms of your thoughts and some further discussion about this particular topic. So to wrap up, this patient actually did really well, the one I was mentioning to you. And we were able to fix his parastomal hernia and he did really well, and he's been doing well for about a year and a half now. So we can get good outcomes, we just got to be careful when you finally decide to fix these and repair these hernias. Thank you.

Morgan Stout:

Thank you so much, Dr. Poulose, that was incredibly informative.