UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LITIGATION	16-md-2753-LM October 27, 2017 8:45 a.m.

REDACTED TRANSCRIPT OF SPECIAL HEARING
BEFORE THE HONORABLE LANDYA B. MCCAFFERTY
AND
THE HONORABLE CHARLES S. TEMPLE

APPEARANCES:

For the Plaintiffs:

Jonathan D. Orent, Esq.
Motley Rice, LLC

James B. Matthews, III, Esq.
Blasingame Burch Garrard & Ashley

David Selby, II, Esq.
Bailey & Glasser, LLP

Susan A. Lowry, Esq.
Russell F. Hilliard, Esq.
Upton & Hatfield, LLP

Anne W. Schiavone, Esq.
Holman Schiavone, LLC

D. Todd Mathews, Esq.
Gori Julian & Associates, PC

Adam M. Evans, Esq.
Hollis Law Firm, PA

APPEARANCES CONTINUED:

For the Defendant: Enjolique D. Aytch, Esq.
Rebecca Ocariz, Esq.
Hugh J. Turner, Jr., Esq.
Akerman, LLP

Pierre A. Chabot, Esq.
John E. Friberg, Esq.
Wadleigh, Starr & Peters, PLLC

Court Reporter: Susan M. Bateman, LCR, RPR, CRR
Official Court Reporter
United States District Court
55 Pleasant Street
Concord, NH 03301
(603) 225-1453

P R O C E E D I N G S

THE CLERK: The Court has before it for consideration today a special hearing science day in Civil Case 16-md-2753-LM, In Re: Atrium Medical Corp. C-Qur Mesh Products Liability Litigation.

JUDGE MCCAFFERTY: All right. Good morning all. It's good to see everybody.

We have a number of people via phone listening in. However, the Court has muted the phone so we don't have music interrupting our hearing as we did at one of our last hearings. So we do have a number of folks who are listening in and hopefully can hear everything that we're saying.

We will have a transcript of this science day that will be made available to everybody involved in the case, parties, litigants, and the PowerPoint will be made an exhibit so that people who are listening and want to look back over moments in this hearing, parts of the transcript, and match it up with various exhibits, they'll have the opportunity to do that.

My understanding is that plaintiffs are going to occupy the first hour and a half, defense counsel will occupy the next hour and a half, and we envision this taking essentially the morning.

Okay. So I'm pleased to welcome Judge Temple to our courthouse and to preside with him today for this science

day.

It's a little warm in here. We're hopeful that they will be pumping some cool air in soon so hopefully you'll feel some relief from the heat. I can feel it up here already.

JUDGE TEMPLE: It's hot.

JUDGE MCCAFFERTY: All right. So without further adieu, let me turn it over to plaintiffs' counsel.

MR. HILLIARD: Thank you, your Honor. Good morning, your Honors.

As it may please the Courts, my name is Russ Hilliard, I'm plaintiffs' liaison counsel, and I just want to introduce the two attorneys that will be making the presentation this morning on our behalf.

First is Attorney Jonathan Orent. He will do the first half of the presentation, then followed by Attorney James Matthews.

JUDGE MCCAFFERTY: Thank you. Good morning.

JUDGE TEMPLE: Good morning.

MR. ORENT: Good morning, your Honors.

I would just like to introduce my colleague, John Knowles, who will be running the technology for me this morning.

JUDGE TEMPLE: Good morning.

MR. ORENT: So it's estimated that about 5 percent

of the population will develop an abdominal wall hernia over the course of their lifetime, but 70 percent of hernias that develop are related to the inguinal area.

JUDGE MCCAFFERTY: Say that again.

MR. ORENT: About 70 percent of hernias that develop are inguinal hernias as opposed to ventral or abdominal -- true abdominal hernias, more in the groin if you will, but 900,000 plus, almost a million surgeries are done a year to correct hernias in the United States.

There are several major types of hernias. Starting with the highest up in the abdomen is the epigastric. That's at the upper abdomen above the midline or at the midline.

Then you have incisional hernias which often occur at the site of surgeries like prior C-sections or other abdominal surgery sites where there's a weakness that develops due to the prior surgery.

You then have umbilical hernias at the navel. Then you have what's called a direct inguinal hernia, which is near the opening of the inguinal canal, and then indirect hernias which are actually at the opening of the inguinal canal. And then finally you have what are called femoral hernias.

As I said before, inguinal hernias are the most common type of hernia. They make up about 70 percent of all hernias. These hernias occur when intestines pushes through

a weak spot. And that's really by definition what a hernia is. It's when intestines pushes through a weak spot or tear in the abdominal wall, and this is oftentimes in the inguinal canal.

So if you look at your screens, this is the depiction of an inguinal hernia. You can see where the inguinal canal is and actually when the herniation, the intestines actually come through that inguinal canal, that's that indirect hernia. If it comes near the inguinal canal but doesn't actually go through, that's what we call the direct inguinal hernia.

And just for landmarks, this is a male depicted here. The herniation is in close proximity to the spermatic cord.

A ventral hernia I think is when we all talk about hernias what we generally think about, and that's a true -- in the stomach area, to use lay terms, and that's a bulge from an opening in the muscles of the abdomen. The hernia can occur at an incision site, as I mentioned before, above the navel, which would be an epigastric, or other spot wherever there's muscle weakness.

As you see here depicted is the intestines coming through the musculature in the abdominal wall protruding below the skin, and the hernia is the hole itself depicted here.

This is a cross-section of an abdominal wall, and what I've added to this picture is the abdominal pressure. So when we talk about hernia repairs, one of the things that's important to understand is that there's a great deal of pressure being exerted in multiple directions, both coming from behind the abdominal wall, but then it's also going to the sides. And so any hernia repair has to as closely as possible proximate and provide support to be able to keep both the organs inside but also maintain strength so as not to reherniate there.

So looking at the different layers, that top layer is skin, the very bottom layer is the peritoneum, and I'm calling that out pretty early on because very much of the discussion today is going to be about the peritoneum and surgeries that go on below the peritoneum. That's one of the very common ways of doing these surgeries is putting mesh below the peritoneum, so I want to just call that piece of anatomy out to you.

Above that there's a layer of fascia and muscle and then another layer of fascia, and then there's the skin and the accompanying subcutaneous fat.

So when you're talking about hernia repairs, there's several different treatment modalities that can be utilized. They can roughly be broken down into two categories, primary suture repair and graft repair or mesh

repair. There are several subcategories of mesh repairs. There are synthetic permanent meshes, biologic meshes, synthetic absorbable meshes and composite meshes. And really what that means is that -- that's just what the graft material is made out of. And when you're deciding what kind of surgery to do on a particular patient, obviously you want to weigh the risks and benefits of each of those procedures.

So traditionally primary suture repair, that is, using stitches, was the mainstay of surgery up until the 1950s for curing hernias.

Beginning in about 1958 surgical grafts really took off and polypropylene mesh quickly gained favor. However, primary suture repair, that is, using stitches, has never been fully replaced and it's very commonly used for small hernias in the two-to-three-centimeter range today, still using the same technique that William Mayo developed over a hundred years ago, and that's called the vest-over-pants approach.

There are some other techniques that are used for primary suture repair today. There are individuals who use steel sutures. In certain clinics that has been a noted successful surgery that has rates very comparative to graft repairs.

Now, it's important to understand there are some studies that have noted very high recurrence rates in hernia

repair without graft augmentation, and that's one of the major reasons why folks are using grafts, to help with surgeries. However, numerous studies indicate that the surgeries involving these grafts actually have a smaller reduction in recurrence than previously believed.

One of the major reasons for that is that the quality of the studies that have been done most recently are actually a better quality of study comparing native tissue or primary suture repair to graft repair. But generally speaking today, the majority of surgeons who do primary suture repairs are doing them on smaller herniations.

JUDGE MCCAFFERTY: Explain graft for me.

MR. ORENT: Sure. A graft is just an implant. It can be anything. It could be an artificial material, like a polypropylene polymer. It could be cadaveric tissue. It could really be anything. It could be anything that's imported into the body to assist, in this case, to assist in the hernia repair. The patient's own tissue could be used. There's a variety of different processing methods and techniques that can be used.

So when we talk about graft repair versus primary suture repair, in terms of risks what we're really talking about with graft repair is a lower chance of recurrence but also a higher potential infection, fistula, mesh extrusion and bowel injury compared to those suture repairs.

Primary suture repairs have traditionally been thought to have a higher chance of recurrence, though it's now thought that it's comparable in some circumstances with certain techniques, but generally speaking it's believed that there is a slightly higher chance of recurrence.

Now, again, when we're talking about surgical grafts, what we're talking about are scaffolds, essentially, to support the tissue. And one of the reasons that grafts are necessary is that connective tissue doesn't actually regrow after fetal stages in life. So scar tissue is what grows back after any surgery, and at a maximum that has about 80 percent the strength of the original tissue that was in the space.

So as scar matures -- and that's assuming the best case scenario, that you're getting approximately 80 percent of that strength to maintain the internal pressures and the lateral pressures.

So mesh or other graft materials are designed to provide a scaffolding. We would like to think about it as rebar in concrete for the repair of soft tissue. This additional structural support is designed to minimize that chance of recurrence.

So with a graft repair -- and in this case I'm going to focus for a little bit primarily on polypropylene meshes. There are two general categories of graft repairs.

One is an open hernia repair with mesh, and then the other is a laparoscopic repair.

So when we talk about an open repair, we're talking about an incision that is made directly over the hernia. And again, we're talking about the hole in the abdominal wall.

The hernia surgeon identifies the hernia sac. And as I mentioned and I called out before, that there is a layer of tissue called the peritoneum that holds all of our internal organs in. So when you hear the term hernia sac, really what we're talking about is peritoneum that is now outside of the abdominal cavity.

So the surgeon first identifies the hernia sac, reduces its contents, that is, the surgeon pushes the hernia back through so that he can identify the defect, the hole in the abdominal wall. Mesh is then placed over the entire area of the hernia allowing a sufficient overlap, and then it's secured in place.

And there are a number of ways of securing it. Often sewing it. There's a newer technique where they use a fibrin glue. Fibrin is a protein in blood that typically is associated with clotting, but the newer fibrin glues allow it to stick in place without using sutures. Then the skin covering the mesh is sewn together and the repair is completed.

Laparoscopic hernia repair begins with three to

five small incisions, each measuring less than an inch. A laparoscope is used, and the hernia surgeon then goes in, looks inside from below the hernia and reduces the hernia, puts mesh in place, secures it with sutures. And the advantages of the laparoscope are obviously quicker recovery time because there's a smaller wound, fewer wound complications theoretically, quicker recovery time, and reduced pain.

And this is an example of what's called an intraperitoneal mesh. So this is below the peritoneum. And you can see, if you're looking at this picture, there are a number of tacks close to the edge securing this particular mesh in place.

JUDGE TEMPLE: Which type of repair is used more often, the open or the laparoscopic?

MR. ORENT: I think more and more surgeons are using laparoscopic repairs, particularly the intraperitoneal approach, but it does vary depending upon what particular subtype of hernia, the size of the hernia, and a variety of other factors, but generally speaking in recent years the laparoscopic intraperitoneal approach has become very, very popular.

And that's actually -- the intraperitoneal approach, which is going below all of the tissue layers right up against the intestines, is actually an approach that was

first developed in the early 1990s. It was very highly controversial in the medical community because for the first time hernia surgeons operating were placing grafts in direct contact with bowel. And this has gained tremendous popularity over the years despite the higher complication rates because it is a theoretically easier surgery to perform, there is a theoretical benefit of quicker recovery times, less pain, and so on and so forth.

If you look at this next chart, and I'm going to go through each of these in turn, here are four examples of the different placement methods for hernia meshes.

So if you look at (a) here, this is an individual who would be standing up, you can see that that yellow line closest to the intestines, that's that peritoneum. So letter (a) is actually the intraperitoneal approach, also called IPOM, and you can see right there that there is mesh which is depicted by the red right up against that intestine.

If you move out a little bit to Exhibit B -- or to the letter (b) there, you're now looking at a mesh which is an extraperitoneal sublay which is right below the musculature in the abdomen.

Letter (c) is actually within, it's an inlay position, it's within the musculature, and then letter (d) is actually on top of the musculature. It's on top of all of the fascia and it's just below the subcutaneous fat and skin.

So again, looking at our cross-section to give you the best view -- again, we're looking at that skin layer, the intra-abdominal subcutaneous fat tissue, and here for the onlay approach that mesh is onlayed on top of the fascia and muscle, and you can see that it is sutured in place here in several locations.

Again, we're looking at an inlay mesh now. This is within that fascia, within that musculature, and it's sutured in place. It is a smaller graft than the onlay mesh.

Here's another depiction of -- this is an underlay. So you're actually directly below the muscle.

JUDGE MCCAFFERTY: I'm a little bit lost on this one. Can you go back and tell me what I'm looking at?

MR. ORENT: Sure. So if you're looking at the green --

JUDGE MCCAFFERTY: Yes.

MR. ORENT: -- that is actually the mesh.

JUDGE MCCAFFERTY: Okay.

MR. ORENT: So that right there, that's the mesh. I didn't realize I could do this.

So the green is the mesh. These are the major muscles. So what you're doing is you're actually inlaying it within the musculature.

Now, the difference is --

JUDGE MCCAFFERTY: When you say difference, the

difference between these two.

MR. ORENT: Correct.

JUDGE MCCAFFERTY: Okay.

MR. ORENT: So with each of these layers -- it's not clearing but --

JUDGE MCCAFFERTY: And there are only two sutures; is that right?

MR. ORENT: Yes.

I clearly didn't focus on working on this yesterday.

But if we look at the different layers -- so here you're actually going down with each position. So that first onlay position the mesh is sitting on top of the different layers. We then move within here, it's moving down one layer.

JUDGE MCCAFFERTY: Okay.

MR. ORENT: It's moving down another layer here to the underlay.

And then finally, with the intraperitoneal approach, you're actually below all of the tissue planes and the intestines would be right here.

So actually, we've prepared some animations to show what several hernia surgeries might look like.

JUDGE TEMPLE: So looking at this one, for instance. There's no depiction of exactly where the hernia

would be, but it would be somewhere below that mesh?

MR. ORENT: Correct.

JUDGE TEMPLE: Okay.

MR. ORENT: So we prepared a couple of videos here that actually will show you what a surgery looks like, and I'll walk you through what some of those repairs look like. I think it will provide a little more clarity.

JUDGE TEMPLE: Thank you.

MR. ORENT: So we're starting off with a laparoscopic inguinal hernia repair.

So in our little patient here you can see -- these are the inguinal canals, and this is an indirect hernia repair. The herniation is actually coming through the inguinal canal.

Now, in this particular patient, this is a very severe hernia. It starts off as being incarcerated.

So you have several different types of severity, but an incarcerated hernia, then this becomes more severe. It actually becomes strangulated. So this doctor is going to use a total extraperitoneal laparoscopic repair.

JUDGE MCCAFFERTY: What does incarcerated mean?

MR. ORENT: Sure. Can we pause this?

So an incarcerated hernia -- so there's really several layers of severity of a hernia.

There are reducible hernias, where actually the

hernia can easily go back in below the surface of the hole.

Then you get what's called an incarcerated hernia, which is not readily reducible, it's essentially stuck, but it's not being cut off, if you will.

By the time you get a strangulated hernia, you're now losing function of that piece of intestine that's now protruding.

So in terms of severity, you start with a reducible hernia, moving to an incarcerated, moving to a strangulated, and a strangulated hernia actually would be an urgent repair that's needed because you're now putting patients in significant danger.

So in this particular patient they're now showing us three laparoscopic ports here, and this is -- again, this is going to be a laparoscopic repair.

And the first thing that occurs is once they make their incisions, they actually fill up the abdominal cavity with CO2. What this is doing is this is going to allow the surgeon to actually then input the laparoscope and be able to look inside the hernia, look inside the abdominal wall. In this case, look inside the inguinal canal and see the hernia.

So the first thing that they want to do is actually reduce the hernia sac.

Can you pause this for a minute, John? Thank you.

So when we're looking at this -- we've been talking

about tissue layer so far. The hernia sac is the peritoneum, and so in this particular depiction the clear little sac, that's the peritoneum. But in this case, you can see where it's going through the inguinal canal, that's the hernia. That's the hernia sac leaving the body.

So in this case the surgeon is first reducing the hernia, that is, bringing the hernia back within the body. And that's what's happening here is they're bringing the peritoneum in, and here they're using the mesh to prevent a reherniation.

Now, that mesh is going to be brought in through the laparoscope and then it's going to be tacked in place all around. We have a later animation that will show that in more detail, but this actually is just designed to show you a little bit of what an inguinal hernia repair is.

Now, we're going to talk about the laparoscopic repair of a ventral incisional hernia, and that again is the -- when I think of a hernia, even though it's only about 30 percent of hernias, I tend to think of ventral hernias, and this is a laparoscopic repair of one of those.

So as you can see, there's a herniation right here where it's actually going through the connective tissue between the muscle. And again, in this individual here is the large and small intestines and the peritoneum.

This is a depiction of the abdominal muscle. So

this is really -- what we were looking at previously in terms of a cross-section, now this is a horizontal view.

So when we think about ventral incisional hernias -- again, an incisional hernia -- can you just pause that for a second -- is a hernia at the site of a prior surgery. So in this case -- this is a scar line. So the hernia is coming through -- this is, again, an incisional hernia, ventral hernia.

And this individual in my experience has a variety of symptoms. But again, looking at the hernia here, you see the hernia sac which is that peritoneum now outside the body.

We're moving from a reducible hernia to now creating an obstruction, and this individual is losing functionality. So they're going to start developing pain, perhaps vomiting, constipation, and so this is going to be a procedure that needs to be done to fix this individual.

As we move into severity, this is now becoming strangulated and presents a danger to this patient if surgery is not done because there now would be a loss of anatomical function.

So in this case several ports are made. These are the small, less than an inch, port, and this individual is being filled with carbon dioxide gas so that the doctor can get the laparoscope in and view the hernia from the inside.

And now they're putting in the laparoscope, which

is the camera. And within the intestines here we can see both the hernia sac, and they're inserting the tools to perform the surgery.

If you could pause here, John.

You can see these are adhesions. So the first part of fixing this hernia in order to reduce this particular hernia, the surgeon first has to clip away and remove the adhesions.

Continue, John. Thanks.

So this surgeon is actually cutting the adhesions, and these are adhesions between the peritoneum and the abdominal wall. He's reducing the hernia. When he cut peritoneum, the hernia sac was cut. He's actually doing a primary closure of the wound here, that is, stitching up the actual hernia before placing mesh on top of it.

Could we go back there for one second? Can you pause that?

And so the mesh is actually going to be tacked in place. The mesh is going to be inserted through the laparoscope, it's going to be rolled up and deployed, and it will actually be tacked in place.

But if you look at the four corners of this mesh, these little round things, those are sutures. They're actually used to lift up the mesh. And I believe Mr. Matthews will show you a little bit more detail on that

later, but this is a mesh that is being depicted being inserted from below that is on top of or below the primary wound closure.

John, can you continue?

They're now going to reduce the CO2 and remove the tools, and essentially the surgery is complete at this point.

So going back to our cross-section to show you -- this is actually all four, and actually we've added a fifth layer in here, fifth subtype by showing the sublayer or the inlay mesh showing two different types of that, essentially.

But these are all in one depiction here. So if you look, the top layer is onlay, then you're going inlay, the retrorectus, so those are the retrorectus muscles, the sublay there. And then you're going underlay, that's the fascia that's directly above the peritoneum, and then finally underlay or intraperitoneal approach, the IPOM approach.

JUDGE TEMPLE: Is there any specific percentage of what mesh, whether it be onlay, inlay, or the other types, that they used in this surgery?

MR. ORENT: So right now with the vast majority of surgeries, I couldn't give you a statistic, but I would say that the vast majority of them today involve the use of mesh as a graft. I would say that the vast majority use polypropylene mesh as a graft.

Now, when we get into the intraperitoneal layers,

those all generally use and require what's called a tissue separating layer, and because you're now up against intestine, you have to prevent that mesh from attaching to the intestine and you need to have a way to do that safely.

So a variety of manufacturers have come up with different approaches, and that's really existed from the late 1990s forward that this intraperitoneal approach has come along where you've needed this second layer.

So some manufacturers use other polymers, like ePTFE, which is essentially a Teflon coating on part of the mesh and then polypropylene above it. Other manufacturers use other chemicals.

In these particular cases Atrium used fish oil, Omega 3 fatty acids, as a mechanism to allow for safety.

So when we talk about tack placement, this is a tool that's used for the tack placement. Once you suture in place, then you want to tack around all of the edges to make sure that the mesh device is securely in place.

Again, you can see here sort of the abdominal walls, the subcutaneous fat, and the skin.

So how mesh works -- and in this case I'm going to talk primarily about polypropylene because that's the most commonly used mesh. And in these cases the C-Qur devices are in fact coated polypropylene meshes, so the concepts behind the use of polypropylene as a graft still apply here.

So once you have an implant, the body begins a foreign body reaction. And the first thing that occurs is blood and debris remains from the surgery, and so that needs to be cleared out. And the way the body does that is by using fibrin and a variety of other processes related to the inflammatory process.

So here the initial implant occurs. There's space -- if you can think about the mesh, there's actually a space where the tissue once was. There's now mesh in that space. There's blood and debris. Essentially that's going to be removed and filled in with initial scar deposition. That's called type 3 collagen, which is a less organized type of collagen than what will ultimately be placed there.

Over time, a matter of weeks, that scar tissue is going to innervate, that is, nerves are going to grow into that scar tissue and it's going to vascularize, blood vessels are going to form in that place.

That scar tissue is going to contract. Over the first four weeks that scar tissue is going to force a contraction of the graft of about 30 to 50 percent.

So we want to talk about -- there's really two types of polypropylene meshes. There's a lightweight large pore mesh and a heavyweight small pore mesh.

Prior to the 1990s heavyweight small pore meshes were widely uses. Now large pore meshes, lighter weight

meshes are used. Sometimes they're called medium weight meshes as opposed to lightweight meshes, but you usually see something on the order of a 1-to-3-millimeter pore size, that is, the hole between pores is usually about 1 to 3 millimeters, and a weight would be in the 40 to 50 grams per meter cubed.

And the design of lightweight large pore meshes, it's designed to reduce the foreign body reaction and to allow healthy ingrowth, because the way that mesh works is actually scar tissue grows between the pores of the mesh and secures the mesh in place, and the scar tissue is now, again, that rebar in concrete. The scar tissue is the concrete, the mesh is the rebar, and you have additional structure and support in theory.

So ultimately on a sheet of polypropylene mesh you're going to get ingrowth from both sides, from the top of the mesh and the bottom of the mesh. Scarring will go through each of the pores. Ultimately that's going to develop into what they call type 1 scar tissue, type 1 collagen, which is a mature scar tissue.

Now, with heavyweight small pore mesh you get a phenomenon called fibrotic bridging, which means that the filaments are too heavy and too close together and that the scar tissue actually overwhelms what healthy scar ought to be and forms a single scar mask, called scar plate, and that can

inhibit anatomic function. It can cause pain. It can cause -- the contracture of the scar tissue actually could cause significant injury due to the nerve pain and creates a much higher rate of foreign body reaction over a long period of time.

So when you're looking at different grafts for soft tissue repair, again, you're looking at -- we've talked mostly so far about polypropylene. We are talking about autografts, xeno or allografts, and synthetics.

So autografts are donor site native tissues. They generally have -- you don't have biocompatibility issues, but it's not a very common usage because there are many patients, particularly patients who may not be in the best of health, who aren't qualified to donate their own tissue from another site and reinforce.

So then you look at xenografts and allografts, which are tissue that are processed, and usually commercialized, that support ingrowth. There's ease of handling. Biocompatibility is greater than a synthetic because a foreign body reaction will go away once that material disappears. It will disappear with time.

Synthetics, on the other hand, stay forever, and they have really good mechanical properties, much lower cost, but there's a higher foreign body reaction making them more susceptible to infection, pain, and ultimately degradation of

the graft itself.

So since the 1950s there's been a lot of studies on the use of grafts in the human body. So the first thing that they learned and began writing about in the 1950s was that any implanted graft device, it doesn't matter where in the body, but we're focusing primarily on meshes, that it must not be physically altered by tissue fluids. What we mean by that is it's chemically inert to the body. It doesn't break down. It doesn't change.

They also learned in the 1970s that the granulation tissue in the body can be formed by friction between the tissue and the implant. Bacteria are protected in interstices. And when we talk about pore size and moving from a small pore heavyweight mesh to a large pore lightweight mesh, the pore size matters because macrophages and neutrophils and other constituents of the immune process and the inflammatory process need to be able to fight off bacteria and allow for healthy ingrowth and replacement of that debris and damaged material, blood, and so -- bacteria, though, can colonize within what are called interstices. Interstices are actually the knots within mesh, if you think about these as being knitted polypropylene. There's a knot between the pores that hold the mesh strands together and bacteria can grow within. Pore size is important for tissue incorporation. It's largely thought today that you need a

1 millimeter effective porosity. Effective is what happens after contracture, that tissue contracture. You need to be left with about one millimeter is what is currently thought.

We've also learned in the 1980s that heat-exposed polypropylene releases biologically active degradation products. It degrades. Mr. Matthews will talk more about that later.

Immediately upon insertion there's a race to the surface between the bacteria and the host defenses. So bacteria is trying to proliferate and macrophages and other inflammatory responses are trying to destroy that. So it's a race to see who wins.

Bacteria can migrate along synthetic polymer fibers. That was 1993. Bacteria can adhere to materials and create a biofilm.

By the 1990s, Dr. Klosterhalfen and his group reported, and it was widely accepted, that polypropylene mesh contracts up to 30 to 50 percent after four weeks and that surface toughness and smoothness promotes the bacterial wicking of meshes. Bacteria can be wicked. And bacterial colonization by 2000 was found in 33 percent of explanted mesh devices.

So when you're talking about a graft device, you want to think about a variety of factors in making sure that you're using the best device possible for your patient, and

you would want to look at the tensile strength, because you're dealing with the body, body pressures, and you want to make sure that you're going to reduce the chance of recurrence. That's the entire reason for using a graft.

Pliability, that can also be thought of as elasticity. The body has a certain range of motion that it needs to accomplish, and so you don't want to inhibit the body's natural movement. It needs to be biocompatible. That is, the body can't reject it. It needs to be easily manipulated. The surgeon needs to be able to go in and utilize this device. It's got to be durable because it's going in for a lifetime.

The tissue ingrowth, it is essential because these devices don't work if the tissue doesn't grow into the device.

It needs to have a controlled infection rate, and it needs to control for post-inflammatory response and minimize seroma formation.

So I'm just going to start briefly on the history of C-Qur, and then I'm going to turn it over to Mr. Matthews.

JUDGE MCCAFFERTY: What's seroma?

MR. ORENT: Seroma would be like a fluid pocket essentially, and so you want to -- a seroma can form and often forms in most surgeries, but it needs to be cleared. The device needs to have the ability to clear that out, and

you don't want to have long-term seroma formation.

JUDGE MCCAFFERTY: Okay. So that's not a good thing.

You mentioned a doctor or a group of doctors at one point.

MR. ORENT: In Germany, yes.

JUDGE MCCAFFERTY: Will we hear that name frequently or is that just something --

MR. ORENT: You might. That group in Germany has published a lot since the 1990s on polypropylene.

JUDGE MCCAFFERTY: What was the group? What was the doctor's name?

MR. ORENT: It was Dr. Klosterhalfen.

JUDGE MCCAFFERTY: Klosterhalfen.

MR. ORENT: K-L-O-S-T-E-R-H-A-L-F-E-N.

MR. JAMES MATTHEWS: Yes.

MR. ORENT: Dr. Klinge and Dr. Junge, J-U-N-G-E.

Is he part of that group?

MR. JAMES MATTHEWS: Yes.

JUDGE TEMPLE: What was the second one?

MR. ORENT: Klinge, K-L-I-N-G-E.

JUDGE TEMPLE: Thank you.

MR. ORENT: They're in a group outside of Auckland, Germany, that's published very heavily on this.

JUDGE TEMPLE: You mentioned tensile strength. Can

you explain that for me?

MR. ORENT: Sure. Tensile strength is actually the strength of material. So if you think about a backpack, for example, when we talk about tensile strength, it's the ability to hold the force of whatever material might be in that backpack. And so the tensile strength of the mesh, it needs to be strong enough to be able to absorb the body's pressures, but you don't want it to be too strong because if it's too strong you're over-engineering the device and you're going to limit motion. So there's a very fine balance to be had between all of these different properties.

JUDGE MCCAFFERTY: In terms of this timeline, can you put that in any context for us in terms of all of these various things that are discovered, how does that affect -- is this affecting the different types of manufacturing of mesh? Are companies learning about these new bacteria studies, et cetera, and then they're reformulating the mesh?

MR. ORENT: Correct. All of this knowledge, and I stopped intentionally at 2000, this all predates anything that occurs in this particular case.

But over the 1990s through the early 2000s, and actually through to today, meshes are designed with these concepts in mind. These are all well-known concepts.

In fact, the group that I mentioned has consulted with Ethicon, one of the Johnson & Johnson entities that

makes some of these devices. They've consulted with others.

These are concepts that have been utilized in the design of meshes and have fueled the movement away from small pore, heavyweight meshes to lightweight large pore meshes, and each iteration of these meshes as they develop over the years they're taking advantage of the latest science, or attempting to.

JUDGE MCCAFFERTY: Okay. It says bacteria protected and it talks about bacteria migrating and then adhering, and then the last one is bacterial colonization is found.

MR. ORENT: Right. So what they've done is they've actually gone back and looked at explants of hernia meshes and done pathological studies of them. And when this particular group did a study of explanted hernia meshes, they found that about a third of them actually had the presence of bacteria.

JUDGE MCCAFFERTY: Now, some bacteria is good bacteria. These are bad bacteria?

MR. ORENT: Right. This is actually supposed to be an area where, you know, we are in a clean space, if you will.

JUDGE MCCAFFERTY: Okay.

MR. ORENT: There's not supposed to be free-floating bacteria within this area. These are bacteria

that are harmless bacteria. They're pathogens.

JUDGE MCCAFFERTY: So that would be a negative result. And so what would happen as a result in 2000 of this finding? What would happen?

MR. ORENT: Well, in this example one of the things that -- again, we're moving from a smaller pore to a larger pore. The idea is that you want to allow for the immune system to handle the bacteria.

Other surgeons have taken note of this, and some surgeons actually will dip and soak their mesh in an antibacterial substance for a period of time before actually implanting it in the human body.

But this is, you know, a finding that really affects the design of the meshes. So pore size being the largest element here.

JUDGE MCCAFFERTY: All right. And so pore size becomes larger after 2000?

MR. ORENT: Well, it's sort of moving. So in 1997 a doctor by the name of Ahmed publishes original classification of meshes where he called .75 millimeters, or 75 microns, large pore.

That system is largely archaic now, as we've now found that because of mesh contracture, you need to start with a larger pore because you're going to end up with a smaller pore. So the idea is that you want your mesh pore

size to be like 1 millimeter by the time contraction is done. So that's why a lot of these newer meshes are 1 to 3 millimeters in pore size.

JUDGE MCCAFFERTY: Okay. And then some of what ultimately is going to happen in our case is going to try to deal with some of the findings that were made in 2000, 1999.

MR. ORENT: So all of these concepts are concepts that play into the design of these devices that ultimately these devices and manufacturers should have an awareness of such that when they're designing their products, they need to be designed to withstand each of these items.

Our contentions in this case will be ultimately that there are some design flaws with the devices that do not overcome these items, but this is what we believe the state of the science was by the year 2000, and I think that this is all generally accepted information, and it has continued. I mean, we stopped at 2000 because we thought that that was an appropriate place to stop. Because of the contentions in this case, we wanted to stay away from any area that might be controversial. So we stopped, figuring that 2000 was far enough away from the beginning of some of the key facts in this case, that this should be a relatively noncontroversial knowledge that was out in the peer review public world.

JUDGE MCCAFFERTY: Okay. So one of the disputes here will involve fish oil, Omega 3.

MR. ORENT: Correct.

JUDGE MCCAFFERTY: When is that introduced?

MR. ORENT: Mr. Matthews will talk about that in a little bit, but that's introduced later. That's a method of applying a tissue separation layer in the 2000s to prevent adhesions and to minimize the inflammatory response.

So that's applied later, but this is all foundational building blocks up to this point in time.

JUDGE MCCAFFERTY: Okay.

MR. ORENT: So just to finish up before I turn it over to my colleague.

One of the things that we thought was important to understand, because my colleague is going to be talking about the 510(k) process a lot, that is, the FDA, what role does the FDA have in all of this. And so as part of the history of these devices it's really important to understand what the FDA does and doesn't do.

And so there's really two processes the FDA uses to approve or clear a device. What we've put out is the Congressional Research Services publication on the FDA. And these two processes are often confused.

So the first process is PMA, which is premarket approval. And when we all think about medical devices, we all think inherently that every device that we put on is a safe device, that the FDA has done this traumatic amount of

testing, that it's been studied, that there's a gigantic building outside of Atlanta where 60,000 people work and are spending thousands of hours on every device looking at hundreds of hours of human data that's been collected over a long period of time, and that's actually just not the case. Most of the devices that are sold in the United States are sold under a 510(k) process.

Now, what 510(k) is, is that the FDA determines that a device is substantially equivalent to another device whose safety and effectiveness may never have been assessed.

So in 1976 the FDA laws that govern the regulation of medical devices was passed. Devices that predate that time were grandfathered into the market. So there is something called a predicate device that every medical device has, and if you follow a device back through the chain, you'll get to that original device which was either PMA'd or it was grandfathered by the 1976 act.

So when we talk about this, substantial equivalence, when a company launches a new device, it does not have to demonstrate safety or efficacy in the absolute sense. It merely has to show that that device is substantially equivalent to that prior device that it's relying on.

So in practice, unlike premarket approval, the 510(k) process focuses solely on the device's substantial

equivalence. And according to the FDA and the Supreme Court, when the FDA finds a device substantially equivalent to a predicate device, it's done no more than find that the new device is as safe and effective as the predicate.

Most often there are no systematic studies, no human studies done of 510(k) devices. In fact, most often these devices have never been implanted into a human being before they're sold on the market.

So as you see, most of the studies supporting 510(k) submission are not clinical studies. What that means is they're not human studies. They're done in a petri dish. Substantial equivalence in many cases means only that the device performs in similar fashion to the predicate under a similar set of circumstances. As a result, many devices never have to demonstrate safety and effectiveness through clinical studies.

In addition to not requiring clinical studies, three other characteristics mark the 510(k) process which make it less rigorous than PMA.

One is premarket inspections of how devices were manufactured are generally not required, and that's going to be ultimately important in this case.

Post-market studies are not required by the FDA as a condition of clearance.

And finally, FDA has a very limited authority to

stop the sale or withdraw clearance of a device if it's found to be unsafe or ineffective.

So those are the hallmarks of the different processes. And with that, I'm going to turn this over to Mr. Matthews to complete the presentation for the plaintiffs today, and he's going to focus primarily on the C-Qur devices and the complications that can occur from implants.

MR. JAMES MATTHEWS: May it please the Courts. I think that's the first time I've ever said that.

There are currently over a hundred different hernia mesh products. When I say a hernia mesh product, that includes these composite devices that we're going to be talking about today that include both polypropylene and something added as a coating. There are over a hundred in all.

As background, all the early hernia meshes were made from polypropylene plastic net, and I'm going to show you one in a minute, but it's basically a net so that it looks like that. You can envision like a tennis net, for example. It looks kind of like that. It has holes in it, pores in it. And later other polymers were introduced. For example, there are polyester hernia meshes. There are what John referred to as PTFE, or the Teflon is polytetrafluoroethylene, but you'll hear PTFE as we go through this case possibly.

But the main ingredient is polypropylene. Most companies have used polypropylene for their hernia meshes. And C-Qur mesh, the mesh part of the C-Qur is made out of polypropylene.

So with the advent of the laparoscopic surgery that you saw earlier and the placement of hernia devices inside the peritoneum, as you saw earlier, there were developed these new tissue-separating meshes, or we call them composite meshes, and these are the ones that have the barriers on them on the side where the intestine was so that the intestines could not grow into the mesh. That would be a bad thing because then the intestines can rupture, the mesh can erode into the intestines. So you don't want the intestines to grow into the mesh, and you don't want that pure polypropylene to be touching the mesh.

It's also been found, it's undisputed I think, that polypropylene by itself causes dense adhesions, and adhesions are the scars that would grow between the intestines and the polypropylene or the omentum, omentum is the fatty tissue that covers the intestines, and the polypropylene.

There are adhesions in almost every surgery, and what the surgeon can do with these adhesions when he has to separate organs or separate intestines, he can just take his finger and knock these adhesions away, like they're flimsy. Some are not so flimsy and you need to cut them. Some are so

dense that it takes forever, hours, to cut through them. And one of the issues that we're going to have in this case is the dense adhesions that the plaintiffs will allege are caused by this particular product.

In C-Qur the base mesh is polypropylene, as I said. It's called ProLite. And ProLite mesh is a polypropylene mesh with pores that are .8 millimeters.

JUDGE MCCAFFERTY: Can I ask you a quick question.

MR. JAMES MATTHEWS: Sure.

JUDGE MCCAFFERTY: So the adhesions that you're talking about -- and the surgeon is going in before putting the mesh in and sees the adhesions, but you just talked about the mesh actually causing dense adhesions.

MR. JAMES MATTHEWS: Correct.

JUDGE MCCAFFERTY: And I'm confused as to --

MR. JAMES MATTHEWS: If you were to go into me right now, and I have not had any abdominal surgery yet, and you were to scope me, I may have this connective tissue, these adhesions that are connecting the peritoneum to my intestines or holding my intestines together, connecting my intestines together, but those adhesions would be so flimsy that I could take my finger and knock them down or I could clip them very easily. Those are normal adhesions.

The adhesions that I'm talking about that form when polypropylene is in the body are very dense scar tissue. So

it's two very different types of adhesions. But you're going to see adhesions in almost every surgery, and in some of these cases the surgeons describe adhesions in people who have never had surgery before.

JUDGE MCCAFFERTY: Okay. So the dense adhesions caused by the mesh, that's been discovered in a subsequent surgery?

MR. JAMES MATTHEWS: Yes.

JUDGE MCCAFFERTY: Okay. So going back in to repair something.

MR. JAMES MATTHEWS: Correct. So if there was a problem and the surgeon went back in and he saw the mesh and he saw these adhesions attached to the mesh and attached to the intestines, I'm going to show you a picture of one in a little bit, but that would be something that would be subsequent to the first mesh surgery.

And the C-Qur products -- and Atrium makes a pure polypropylene mesh. I'm going to show you that in a minute.

But in the C-Qur products the polypropylene mesh is coated with a thick gel or fish oil and it's actually coated on both sides, so that there are no pores once that fish oil is on both sides. The idea would be that this fish oil would go away over 90 to 120 days and then you would have pores and there would be tissue ingrowth. And I'm going to get into more in a little bit about how C-Qur would contend that the

mesh would fixate to the abdominal wall, but I'll get to that in a minute.

But the basic components are the polypropylene and the fish oil. Those are the two things that we're going to be talking about. Is it okay if I move around and show you a mesh?

JUDGE MCCAFFERTY: Okay.

JUDGE TEMPLE: That's fine. Sure. Yeah.

MR. JAMES MATTHEWS: So this is a ProLite mesh, so this would be the pure polypropylene mesh, and this is -- actually if you're in the operating room, this is what the nurse hands the doctor.

So if you open the box -- can I approach?

JUDGE TEMPLE: Yeah, absolutely.

MR. JAMES MATTHEWS: You can see I have a lot of them in here, but these are the instructions for use that come in every box. You'll see these in everything, and these are going to be important in this case. They're in a hundred different languages but the first page is the English language.

They include more than just instructions. They include warnings, adverse reactions, things like that, but those come with every one.

Then this is what the -- this is the pure polypropylene mesh. So there you can see it. I've got a

magnifying glass here if you want to look at it up close, because you can actually see the pores when you do that.

So that's all polypropylene right there. So that's the basic first component that we're talking about.

JUDGE TEMPLE: Just remind me again from Attorney Orent's presentation, when did the fish oil application come into play?

MR. JAMES MATTHEWS: I was going to get into that. This is something that's unique to this particular product, and it was first put on the market limited release in 2006 and major release in 2007. So this product or this category of products made by this company is the only one that has fish oil as the barrier.

JUDGE MCCAFFERTY: Okay. And that fish oil actually covers the pore that we would see in this?

MR. JAMES MATTHEWS: Yes. And I'm going to show you another one in a bit.

The current slide in front of you shows the mesh that you've been looking at and that's the ProLite mesh. And as we've talked about already, these are called tissue separating meshes. And the idea is to prevent adhesions, prevent ingrowth of the intestines into the mesh, yet you want to have ingrowth into the backside of the mesh because when the mesh is put in, what eventually holds it in place is tissue growing into the pores. That's what holds it there.

It's like -- well, there's an ad from Atrium that I'll show you in a little bit, but if you put concrete squares out in your yard, grass will grow up between those, and in this case if that grass covered those squares you would have adequate tissue ingrowth. So that's what you wanted with these meshes. You want it to hold it in like that.

They put tacks in, but in most cases these tacks are absorbable so they go away, and they put sutures in but those sutures go away, so something's got to hold that mesh into place. And that's really what this case is about, and I'll get to that in a minute.

JUDGE TEMPLE: How long does that process take?

MR. JAMES MATTHEWS: Tissue ingrowth?

JUDGE TEMPLE: Yes.

MR. JAMES MATTHEWS: You can have adequate tissue ingrowth within 2 to 3 weeks. It doesn't take that long. But you have to have something for the tissue to grow into.

The next slide is a C-Qur product, and I'm going to show you some of those in a few minutes, but this is just what it looks like with the coating on it. And so this is a ProLite mesh that you just looked at but it now has the fish oil on it.

The next slide is a similar product, but this is actually one of their lighter products that had less fish oil

on it, and you can see there is less fish oil there but still no pores on that side.

This is an ad that was in General Surgery News, and on the left side of the slide there is where I got the concrete block with the grass growing through it idea because it came from their own ad there, one of Maquet's ads. And you can see they've got a little fish made out of fish oil down there in their ad, but what it says is that this -- and I've been calling it fish oil but it's a, according to this ad a bioabsorbable Omega 3 fatty acid coating. And as I said before, that's the only mesh with this particular coating, and it's represented that the coating is bioabsorbable Omega 3 fatty acids, fish oil that we would take as a supplement. That's what this is.

You asked a question earlier about when it was released, and it came on the market in 2006. I think I've talked about how it's coated on both sides.

The way the fish oil is attached to the polypropylene is through a curing process, a heat curing process, and I'm not going to go into all the weeds of that but it's a crosslinking process and that is supposed to hold that fish oil onto that polypropylene. So it's heated to go onto the -- and cured to go onto the polypropylene.

And the initial product was introduced in 2006, but there have been several added to the product line over the

last few years and I'm going to show you some of those in a minute.

[redacted] There are thousands of different kinds of polypropylenes. There's not just one polypropylene.

This is what polypropylene looks like before it's melted. So actually what this is is fish oil. This is the only thing that CVS had that looked like this. This is fish oil tablets, but that's exactly what polypropylene looks like except it's clear, and [redacted]. It comes like that. It comes in huge crates or boxes.

[redacted]

[redacted]

And then that knitted mesh would be sent to Atrium, at this time in Hudson, New Hampshire, and that's when the fish oil was applied. [redacted] That's what kind they had last night at the drug store.

[redacted]

[redacted] And so just so you know, that's coming up down the road. We don't need to get into it right now. It's just what the plaintiffs are going to look into or allege.

JUDGE MCCAFFERTY: Can I stop you for just a moment? It's 10 o'clock, so I'm going to let everybody just take a brief morning break and then we'll come right back. Let's say 10:10, give you ten minutes, be back at 10:10.

(RECESS)

JUDGE MCCAFFERTY: We'll take one more break so that the defendants can get set up.

MS. AYTCH: Thank you, your Honor.

JUDGE TEMPLE: Attorney Matthews.

MR. JAMES MATTHEWS: [redacted]

[redacted]

I'm being very general here. There are a lot of different -- not a lot, but there are several different iterations and different kinds of C-Qur devices. This is just the modified C-Qur flat mesh device that I'm talking about right now.

If you look at it under a microscope, and this is

looking at it from the side or what a doctor would call a sagittal view, the bottom part there, let's see if I can do that, yeah, right there, that's the smooth fish oil side that faces the intestines. And the top part, up here, that's the opposite side that faces the abdominal wall. And so you can see that the bottom side is smooth, the idea being that that would prevent these adhesions because it's smooth, and the opposite side is rough, the idea being that tissue could grow into those spaces and hold the mesh into place.

Plaintiffs will contend that tissue can't grow into those spaces because there are no holes there. It's just rough and so it will not hold, and that will be one of the fights in this case I suspect.

So now I'm going to go through some of the different kinds of meshes that were made. That's just kind of a trademark there.

This is a video, and it shows one of the meshes, but it's also a pretty good illustration of what Mr. Orent covered a little earlier of how this stuff goes in, but it will show you how it actually gets in on this particular video.

And this is something that we just found on YouTube. So you can see there's the smooth side and the other side was the rough side. There's the smooth side. So now we're going to do a hernia repair close to the umbilicus,

or the belly button.

Stop.

So right before the mesh rolled up there, you saw these white lines? Those were the sutures. And they're in the 12 o'clock, 3 o'clock, 6 o'clock, 9 o'clock position. And Mr. Orent showed you the bottom side of those sutures before. This shows where they actually go, and you will see how they're pulled through -- the surgeon stands outside and pulls the sutures through the body and pulls the mesh up to cover the hole in the muscle tissue. In order to get the mesh through the trocar, through the laparoscope, it has to be rolled up like this.

So go ahead.

So it's rolled up and then it's stuck into the trocar. And that guy's belly's not usually that big. It's been insufflated with carbon dioxide.

So then it's unrolled, and that little hole up there represents the defect in the muscle tissue or the fascia, and you can see the sutures being pulled up right there. That's what I was talking about. And then that's supposed -- and then the tacks are put in.

Stop.

So these tacks are going to be an issue in this case too. I'll briefly explain why.

There are two kinds of tacks. There are permanent

tacks and there are -- which are mostly metal, titanium, and there are absorbable tacks. And the absorbable tacks absorb or go away supposedly around 30 days.

The C-Qur fish oil coating absorbs or goes away supposedly in 90 to 120 days.

If you put a tack in that goes away in 30 days, you're left with a fish oil coating on two sides mesh with nothing holding it on because those sutures have dissolved too. At least that's what the plaintiffs will allege in this case.

In some of these -- now, all of the C-Qur devices are not made to go in intraperitoneally, they're not made to go in like this, but most of them are, and we'll show some in a minute that do not go in intraperitoneally. They go in a layer up or another layer up as Mr. Orent showed you earlier.

Okay. Is that it? Almost? Okay.

So as I said before, the first C-Qur came out in 2006 and it was -- the base mesh was ProLite Ultra. Its pores were .75 millimeters, less than one millimeter, [redacted]. It was coated with fish oil, and I think I have -- I think I have one of those. Can I approach?

JUDGE TEMPLE: You sure can.

MR. JAMES MATTHEWS: So again, it comes in a box like this, and I think this might be a big one. There's

instructions for use in here again, there they are, and then this is obviously for a large hernia or hernias. So now you'll be able to see about the coating, you'll be able to feel the coating and you'll be able to feel the rough side. So this would be the smooth side. This would be the rough side there. Polypropylene is in there, too. You can look at it with that if you want to. It might be better than me just showing you or talking about it.

So that's pretty much what we're going to be talking about for the next months or however long, years, whatever. That's our product.

There's another product called a C-Qur Edge. I have one of them over there, but in the interest of time I'll just show you the picture of this one. It has around the edge -- as you can see on the slide, there's more polypropylene sewn around the edge where the tacks would go. And it's still a ProLite Ultra polypropylene but similar device, and then there is the second iteration.

C-Qur came out in 2009. This one had slightly larger pores. It had .8 millimeter pores. This was a heavier weight mesh. And there are going to be expert issues in this case about the density or the weightness of the mesh. 85 grams per meter squared is considered high moderate or heavyweight mesh, and there will be allegedly scientific reasons why that's not good. It decreases the ability for

tissue ingrowth and can increase adhesions, so say the plaintiffs. This had 53 percent less coating on it than the C-Qur Edge did.

This is a different kind of mesh for -- I shouldn't say mesh but a different kind of medical device that includes polypropylene and mesh for smaller hernias, particularly umbilical hernias, but smaller epigastric hernias too.

An umbilical hernia occasionally -- or I actually saw somebody like this the other day and pointed it out to my wife, who was not real happy that I did, but if you're at the beach and you might see somebody whose belly button is an outie. That's an umbilical hernia. And you can have small outies or large outies, but this is for a smaller umbilical hernia. And I think we have a video of how to put this in too, because this is a different way to put things in and this is not always or almost never is intraperitoneal.

But you have one layer of the C-Qur and then you have a C-Qur light mesh circling this. You have two different types of C-Qur meshes on top of each other here with these positioning straps.

This has audio to it. Do we need to do anything to do that? Okay. And it came from this company in the bottom left-hand corner there. So it came actually from a doctor on his hernia mesh website. I'm not going to talk. I'm going to let you listen to the explanation. It will be better than

mine.

(Video played)

Okay. So what will happen -- those long things will be cut off and sutured there and that's what's supposed to hold it in place temporarily until the tissue ingrowth occurs. And I do have one of those, and I have also a TacShield which is another kind of mesh which came around in 2010. And it's kind of interesting to see the difference in the TacShield and the previous mesh that I showed you so if it's okay, I'm going to come open one of those too. I don't want to open everything and take a lot of time, but I think it's good to see some of these.

This is the V-Patch for the umbilical hernia. You can see it's smaller and it has those pull tabs on it. And it has that extra coating.

This is a competitor device. This is actually a Bard hernia mesh that I'm going to show you now so you can see the difference. It's from a different kind of device, but this one is coated on one side. And this is a Bard hernia patch. It's basically the same, but it doesn't have -- it's got a little ring around it too.

And then since it's on the screen and so you'll see the extra coating of polypropylene around the edge, this is the TacShield. These are the shield tacks. I suppose that's why it's called TacShield. So it has an extra layer of

polypropylene around the edge of it. You can see --

JUDGE MCCAFFERTY: Can a surgeon decide to reduce the size of this, or does the surgeon just order a particular size for a particular surgery.

MR. JAMES MATTHEWS: Well, the big one that you have in your hand, the surgeon can cut it, yes.

JUDGE MCCAFFERTY: Okay.

MR. JAMES MATTHEWS: Yes. And it's in the instructions for use that you can trim it to fit what you need.

On the TacShield devices, I'm just guessing it would not be advisable to cut it because that extra layer of polypropylene is supposed to be there to help those tacks stay in, I believe, and so I don't think they recommended that that be cut. But the larger flatter versions, yes, you could cut those and trim those for whatever size you needed.

There's another version of the C-Qur, it's called a Mosaic. And the Mosaic was not coated through and through, so there were little tiny holes in it in different places. I do have one of those, but you're probably tired of me handing you meshes now so I'll show a picture later on I think -- you can't tell from this picture, but you can actually see little tiny holes in places in the Mosaic. So there was less fish oil coating, greatly less fish oil coating on the Mosaic, and you can actually see all of the way through it.

There are -- in state court there are no Mosaic lawsuits filed. I don't know how many are filed in the MDL, but the Mosaic was a later iteration of the product.

And another later iteration was called C-Qur FX, the FX stood for filament coated, and the reason it's FX is because now you don't have a solid sheet of fish oil on both sides. You only have those filaments coated. So it's only dipped and only the filaments are coated so you now have pores in the C-Qur FX.

You also have it in the C-Qur Century FX, which was for inguinal hernia repairs. Inguinal hernia repairs, without getting into it, are a little different. A lot of the inguinal mesh devices are three-dimensional, they're not flat. They're almost like a parachute or even a badminton birdie, some. This one's not, but it has a three-dimensional aspect to it because of the shape of the groin, frankly.

So common adverse events associated with hernia mesh repairs are frankly the ones that appear on the instructions for use in these C-Qur products, and the instructions for use and the brochures that go along with these products are going to be key things that we talk about in this case. Whether they're adequate or not is going to be an issue in these cases.

But this comes right out of the C-Qur instructions for use, so it tells you that you can have inflammation. You

can have infection. We talked about seromas earlier. Seromas are simply pockets of fluid. You can have a hematoma or a blood clot. A fistula is a connection between two things, and in this case it's the connection between -- it usually signifies an infection, and it would be a connection between possibly an infected mesh and an intestine so there's a hole there, or mechanical disruption of the tissue, which you're going to have if you have surgery, or disruption of the mesh material, and then it says possible adhesions if placed in direct contact with the viscera and the organs.

So that was C-Qur's warning. These are the adverse events that plaintiffs will claim in these cases, the most important thing being the frequency and severity of these.

There is no information in the instructions for use about how frequent or how severe some of these can be, and that will be a bone of contention in these cases.

I'm not going to go into details now, but some of the things that I'm going to talk about, briefly I hope, are infections. And I'm not just talking about normal infections that can sometimes occur with surgeries. I'm talking about a greatly increased heightened risk of infections with the fish oil product.

There were abscesses which go along with infections. There were actually people who developed skin rashes, not a few either. It was not an infrequent event.

Skin rashes on the outside of their body with these devices.

We've already talked about dense adhesions. I'll show you one of those in a minute.

A meshoma is when the mesh contracts and balls up. It's not attached. It didn't have tissue ingrowth and so the body moves. You have defecation, you jump up and down, you walk, you might pick up things at work, all kinds of things move the abdomen, and the mesh can move like that and ball up and that's called a meshoma. And so we see those.

When you have a meshoma or you have migration of the mesh when it doesn't stay fixated, the bowel -- the intestines can be entrapped or pinched off and you can have bowel obstructions. Some of our cases people had to have pieces of bowel removed, and so you would have an anastomosis where you sewed bowel back together again. Then if the mesh moves or migrates, obviously you could have a recurrence because you still have a hole there. And if the mesh uncovers that hole, your intestines can pop right back out. And there's going to be pain associated with almost all of these issues.

This particular slide actually doesn't have anything to do with tacks, but you can see it's tacks, and those are permanent tacks that are in this particular mesh.

JUDGE MCCAFFERTY: Not quite a scientific question, but just wondering. These warnings come with a product.

Obviously the surgeon or the doctor -- the assumption is standard of care would be the doctor would communicate to the patient these are the possible adverse reactions?

MR. JAMES MATTHEWS: That would be the hope, yes. I frankly think that there will be cases where the defense alleges that the doctor did not properly communicate those and possibly blames the doctor. Maybe not, but that's what happened in the vaginal mesh cases. So, yes, those are the things that a doctor would want to communicate to a patient.

JUDGE MCCAFFERTY: Thank you. You can go ahead.

MR. JAMES MATTHEWS: We will allege that there are other things that should have been communicated.

JUDGE MCCAFFERTY: And are surgeons -- do they normally have a variety of mesh products or do they tend to go with one?

MR. JAMES MATTHEWS: That's the first question I asked whenever I got involved in these cases. This is what typically happens. You have sales reps that call surgeons and call hospitals, and a lot of hospitals have purchase agreements with individual companies. So you may have a doctor who wants to use a C-Qur mesh. He just wants to for whatever reason. But the hospital has a contract with Bard. Bard is the largest mesh manufacturer. They have the biggest market share. And so all they have on their shelf is Bard products, so that surgeon has to use a Bard product.

There are instances in cases we have where the surgeons had to use a C-Qur device because they didn't have any other ones there because the chief of surgery said, I want to use those, because sales reps had called on him and convinced him to do that. It goes a little bit deeper than that, and a lot of heads of surgery departments are also consulted through mesh companies and get paid so they make their hospitals use that mesh if they can.

So, no, the individual surgeon doesn't always get to choose the mesh. It might be what was available on the shelf that day, but there are cases where individual surgeons do. In community hospitals the surgeons basically control what the hospital buys. In larger hospitals it can be a contract. Does that answer your question?

JUDGE MCCAFFERTY: Yes. Thank you.

MR. JAMES MATTHEWS: So how do these devices, in particular the C-Qur devices, cause injury. And what we're going to contend in this case is that the volume of fish oil, the density of the coating and what it becomes after it is cured and what it becomes after it's in the body is a mechanism of injury. We're going to say that because it is coated on both sides and has no pores until later iterations, that that's the mechanism of injury because it doesn't allow adequate tissue ingrowth.

Polypropylene is left. I mean, eventually this

fish oil is supposed to go away. I will say that there are cases where over a year later the fish oil hasn't gone away. It's been found floating in a seroma, in a pocket of fluid, and the fish oil is still there. But it's supposed to go away, and if it does go away in 90 to 120 days, what's left? Pure polypropylene right there next to the intestines.

So you have the same problems that you would have if you put pure polypropylene there to begin with, we will say. And the problem with some polypropylenes, not all but some, are that they can deteriorate and degrade, and I'll show you some slides of that in a few minutes -- in less than a few minutes.

Another problem is -- this is intraperitoneal, so it's next to the intestines, and they're made to go like that and that's okay, you can put them in like that, but you'd better have a really good product that doesn't deteriorate and allows active tissue ingrowth if you're going to place it next to the intestines because there are other areas, as you've seen, to place these meshes.

And there was at least initially, and maybe even after that, a lack of uniformity with the coating of these C-Qur meshes. There was no uniform protocol or standard of how thick this coating would be at least initially, at least that's what we believe at this point. Depositions may show otherwise, but that's what we think so far.

And there was a problem with some impurities or contamination, and I'll show you a little bit about that in a second.

So I talked about infections, and we're going to blame most of the infections on the fish oil. One of the things -- one of the reasons that we believe you have infections is that the fluid -- there's always fluid after surgery. Fluid cannot go through the implant because it's coated on both sides. So it's trapped. And a seroma will form. And, yeah, seromas occur in surgeries, but they don't form like these and they go away. Some of these stay there and you have these big pockets of fluid that act basically as a petri dish for bacteria and so you have infections.

And this particular product reduces the pH, the potential of hydrogen, in the tissue where it touches, which means that it increases the acidity in that area, and increased acid is another perpetrator of infections.

In fact, the pH here can be over 30,000 times lower than normal tissue pH, and all of that we will say causes cytotoxicity, or destruction of cells. Cell death is what cytotoxicity means, and it is particularly cytotoxic to mesothelial cells. Mesothelial cells are cells that line the inside of the peritoneum. They're smooth cells. They're there to prevent adhesions. And we think that we will have expert testimony that the fish oil is cytotoxic to those

cells.

So all those things lead up to infection, and I've talked about the density of the coating. One of the problems with infection is what's called dehiscence, and that's when a wound doesn't close. So an incision simply won't close and it will just stay open and infected for weeks or months, and the same processes would occur there.

I mentioned failed incorporation and adhesions. I've talked about meshomas. I talked about dense adhesions, and there's an adhesion.

So on the left is a C-Qur mesh at 7 days, and you can see the suture in the bottom right there. And this is not in a human. I think it's a rabbit or a rat. And there's a slight adhesion formed there after 7 days, but after 30 days you can see that the adhesions have increased on that particular slide and the mesh has contracted on that particular slide. So that's what we're talking about, the contraction.

Now, this is polypropylene. This is a slide of a pure polypropylene right off the spool after it's been knit. So what you're seeing there is where one of the knots is in the polypropylene mesh. This is with a scanning electron microscope. It's very smooth on the outside. And this is what happens when it deteriorates. The outside starts cracking and peeling and then it gets worse like that, and

then it gets really bad like that, and the outside part can actually slough off. There are some more pictures of it there. And that's what it looks like after it's sloughed off on the outside.

So the problem with polypropylene degrading like that is that it increases the surface area of the implant. When there's any kind of implant or foreign body in the body, the body attacks it because it's foreign, and so these cells called macro fascias attack the implant and they're eaters. They are supposed to eat away the foreign body. Well, they can't eat away this. But as Mr. Orent said earlier, they're going there the same time these bacteria are going there. So everybody is racing to get on this implant. And when the implant deteriorates, it increases the surface area of the implant.

It's like the coast of Maine. If it was a smooth coast all the way down, it might be 4 or 500 miles, but I think it's 10,000 miles because of all the fissures in it and the cracks and the inlets and things like that, and the same way here. It has a larger surface area, and every time a piece of polypropylene degrades, it's attacked again. And so once it's attacked again, it degrades again, and then it's attacked again, and this just keeps going. And so polypropylene can actually deteriorate or degrade.

There are different kinds of polypropylene, as I

said earlier, and there are general -- there's general purpose polypropylene. There's industrial polypropylene. There's medical grade polypropylene. There's inflammable grade polypropylene.

Pro-fax 6523 was the general purpose polypropylene. So we're going to have an issue in this case about whether this polypropylene degrades and whether that causes an issue.

And the final issue is impurities in some of the C-Qur products. This is actually one of the meshes that I opened within the last week, and what's circled there is hair that's embedded in the fish oil, and there's several, and I promise we didn't put them there. That was the way it was when it was opened. And I think there are going to be issues in this case about that.

I think that's it. I'm sorry I took so long. But to sum up, the main issues are going to be this two-sided coating, the fish oil itself, and the basic polypropylene that we went through.

JUDGE MCCAFFERTY: Thank you.

JUDGE TEMPLE: Thank you very much.

MR. JAMES MATTHEWS: Thank you.

JUDGE MCCAFFERTY: All right. Attorney Aytch, you would like to have ten minutes to set up?

MS. AYTCH: If you wouldn't mind, your Honor.

JUDGE MCCAFFERTY: That would be great. It will be

11 o'clock, and you're going to be an hour and a half, so we could envision -- it might be more than an hour and a half?

MS. AYTCH: No, we can -- a lot of stuff was covered. As much as we can move forward, we will.

JUDGE MCCAFFERTY: Okay. So it could be less than an hour?

MS. AYTCH: It could be. I don't want to make any promises to the Court.

JUDGE MCCAFFERTY: That's all right.

MS. AYTCH: It could be.

JUDGE MCCAFFERTY: All right. So then we'll just be able to do our lunch break whenever you're finished.

MS. AYTCH: Correct. I don't believe that it's going to interfere too much with the normal lunch schedule.

JUDGE MCCAFFERTY: All right. Well, then let's come back here at 11 o'clock and you can begin your presentation.

MS. AYTCH: Thank you, your Honor.

(RECESS)

JUDGE MCCAFFERTY: Attorney Turner.

MR. TURNER: Good morning.

JUDGE MCCAFFERTY: Good morning.

JUDGE TEMPLE: Good morning.

MR. TURNER: I'm here today with some of my colleagues I want to introduce.

My name is Hugh Turner. Enjolique Aytch is with me, one of my partners. And Rebecca Ocariz is with me, also one of my partners. And in the back is John Friberg, who is from New Hampshire, and Pierre Chabot, who's also with the Wadleigh Starr firm.

We're here and have the privilege, your Honors, of representing Atrium Medical Corporation. And Atrium Medical is the company that manufactured this product, still manufacturers the product, and does so here in New Hampshire, in Merrimack, where they moved over the last couple of years. Originally the company was founded in 1981 by several individuals and the company grew, then finally after 30 years in 2011 it was acquired by a large international life science company. Now it has 500 employees and is in Merrimack where their headquarters are. So they're still a New Hampshire company.

I'm going to split up -- or have asked Enjolique and Rebecca to split up the six topics with Enjolique handling the first three, and Rebecca will handle the second three of those topics.

MS. AYTCH: Good morning, your Honors. May it please the Court, counsel and all attendees.

As Mr. Turner mentioned, my name is Enjolique Aytch and I will present on the topics of what is a hernia, the types of common hernias by location, by severity and how

they're formed, as well as the various treatment modalities. As you know, plaintiffs have reviewed a number of items within these topics already. Therefore, where my presentation may be duplicative or repetitive, I'll try to move through the material fairly quickly so as to not belabor any points.

When my presentation goes into further additional details, however, I will spend my time on those matters. As my partner Rebecca Ocariz states, however, repetition is the key to learning.

Also the presentation style is different views of some of the hernias, so hopefully your Honors will still find utility even where I may be duplicative.

What is a hernia? As previously explained, a hernia occurs when an organ, intestine, or tissue squeezes through a hole or weakness in the abdominal wall, and this weak spot is referred to as a defect.

A hernia consists of three parts, the sac -- let's see if I can do this here, yes, Technology is great -- the sac, which is the pouch, the peritoneum, the covering of the sac, and as well as the contents, which includes the organs, the tissue, generally the intestines or the omentum, and the omentum is a fold of the peritoneum that surrounds the organs and the abdominal wall.

So let's talk about the abdominal cavity. It's

important to understand the composition of it. So even though plaintiffs reviewed this, I will cover it again very briefly.

So the abdominal cavity is the space in the abdomen that holds the abdominal organs. As displayed, this includes the liver, spleen, gallbladder, stomach, the colon or large intestine, the small intestine, the appendix and the bladder. These organs are held together by connective tissue that allows the organs to expand and glide against each other. The peritoneum lines the abdominal cavity and holds the organs in place.

So this 30-second video will demonstrate the contents of the abdominal cavity and how they are not static but are in frequent motion from the activity of the internal body and other activities such as eating, as we see soon that the bolus will pass through the colon here.

So as Attorney Orent mentioned, this is the great amount of pressure that is exerted and that is going on in the abdominal cavity.

The abdominal wall, which is comprised of the skin, a layer of fat, the fascia muscles and here the peritoneum, which is the membrane that lines the abdomen and covers most of the abdominal organs. And this abdominal wall provides containment and support to the internal organs within the abdominal cavity, which is shown here as it is constantly

moving and exerting outward pressure.

The abdominal wall counters this pressure that results in continuous strain on the tissues in the abdominal wall. Certain actions such as coughing, vomiting, straining, and physical exertion can increase the abdominal pressure on the abdominal wall. When this occurs and the abdominal wall can no longer contain the outward pressure, the tissues and the organs can push through the defect or weakness in the wall and this is what creates or enlarges a hernia.

So let's -- let's clear this.

So let's talk about the common types of hernia. There are two common types of hernia by location, as Attorney Orent mentioned, so I will try to move through this quickly.

You have the ventral hernias which are generally at the upper abdominal above the umbilicus, and then you have a groin hernia which are below. The ventral hernias can include an incisional hernia, the umbilical hernia, and the epigastric hernia. And the groin hernias can include the indirect inguinal hernia, the direct inguinal hernia, and the femoral hernia. Any of these hernias can sometimes be visible as an external bulge, particularly when straining or bearing down.

So beginning quickly with the incisional hernia. The incisional hernia occurs at the site of a previous surgical incision and occurs in approximately ten percent of

all surgeries. Certain prior surgeries can include but are not limited to an appendectomy, a gallbladder removal, Caesarean section, et cetera. So these hernias can develop months or even years following a prior surgery. And like all hernias, if it is not repaired early, it can develop into a large complicated defect.

Next we have the umbilical hernia. It and the incisional hernia are the most common ventral hernias. An umbilical hernia occurs in the umbilical area, which is the belly button, where the umbilical cord once passed through the abdominal wall. Women who have had multiple pregnancies have a higher risk of developing an umbilical hernia. Therefore, umbilical hernias in adults are more common in women than they are in men, but obesity is also a risk factor for umbilical hernias so they are not limited to women.

Lastly is the epigastric hernia. Epigastric hernias occur in the upper abdomen at the midline, here you go, and pushes through the abdominal wall between the breastbone and the navel. It is usually a result of a weakness present at birth combined with intra-abdominal pressure along the midline.

It is important to note that hernias do not resolve themselves, except some small umbilical hernias in infants, like what I had said, and as what Attorney Matthews said, we can refer to as an outie anytime that that hernia pokes out.

But as you will see in most young children and infants, it will repair itself.

Other than that, hernias don't generally repair themselves. At best, they can remain the same, but more likely over time they progress and become quite large if untreated. Therefore, hernias can present in various shapes and sizes as depicted in the next slide.

As shown here, in this C-Qur MDL and in the state court litigation, 56 percent of the cases that we have involve ventral hernias as of this week. 42 percent is unknown, which represents the amount of cases that have been recently filed and on the complaint but doesn't disclose what type of hernia it is. However, given the trend, we have reason to believe that the majority of these cases will be ventral hernia cases.

The other common hernia by location is the groin hernia of which there are three common types: the indirect inguinal hernia, the direct inguinal hernia, and femoral hernias.

Inguinal hernias occur at or near the inguinal canal, which is where the nerves and the vessels pass between the groin and the abdomen. They are more common in men than in women because the testicles descend through the inguinal canal after birth and sometimes the canal does not close properly.

The indirect inguinal hernia, which is the most common type of hernia in men, occurs when a loop of the intestine and/or fat presses into or actually through the inguinal canal. This area may be weak at birth allowing hernias to form later in life.

The direct inguinal hernia occurs near the inguinal canal when a loop of the intestine and/or fat presses into a dual weakness in the abdominal wall next to the inguinal canal, and these typically occur in men over the age of 40 and may result from aging or injury.

Lastly, the -- I'm sorry?

JUDGE MCCAFFERTY: I think of hernias as more common in men in general. Is that accurate?

MS. AYTCH: Yes. That is correct.

JUDGE MCCAFFERTY: And why is that?

MS. AYTCH: So the most common type is the inguinal hernia. And so because of the position lowering where there's the weakness from the testicles, that's generally where they occur. However, those are not the most frequent in this litigation.

JUDGE MCCAFFERTY: Okay. So there could be an equal number of male and female plaintiffs?

MS. AYTCH: In this --

JUDGE MCCAFFERTY: Yes, in our --

MS. AYTCH: Can there be or -- I'm sorry. I didn't

hear your question.

JUDGE MCCAFFERTY: Are there more likely to be perhaps an equal number of female and male plaintiffs?

MS. AYTCH: Correct, your Honor, because by far the majority of the cases that we have in both of your Honors' cases are ventral hernias, so occurring upper abdomen.

So the femoral hernia occurs high in the thigh and is due to a weakness in the femoral canal area of the groin. And like ventral hernias, groin hernias do not resolve themselves and can become relatively large if untreated as depicted in the next slide.

And so as we were just discussing, as shown here in the C-Qur MDL and the state court litigation, only 2 percent as of this week represent groin hernias. And again, although we have 42 percent that is unknown, based on the trend it is more likely that those will be ventral as opposed to groin hernias.

Now we're going to discuss hernias by severity. There was mention of this during the plaintiffs' presentation, so I may go through this just a little bit slower just to point them out in this particular order.

So there are the reducible hernias, the nonreducible or incarcerated hernia, and the strangulated hernia.

So the reducible hernia forms a bulge as the

intestine pushes through the hernia sac, but its main characterization is that it can be flattened out upon either lying down or pushing against it. Although there is no immediate danger with the reducible hernia, surgery is still necessary in order to resolve the defect because it's not going to go away or get better on its own.

A nonreducible or incarcerated hernia is where the intestine becomes trapped and the bulge cannot become flattened. Incarcerated hernias can disrupt digestion and require prompt surgery.

And the most serious of the three is the strangulated hernia, which occurs where the intestine is trapped tightly and can result in a loss of blood supply and oxygen and therefore die. These hernias can greatly obstruct digestion and result in significant pain. A strangulated hernia can also be life-threatening and emergency surgery is usually required to quickly repair the defect.

Hernias can also be categorized as congenital or acquired. As the name suggests, congenital hernias form at a point of natural weakness that was present at birth such as the inguinal canal in the umbilicus, where acquired hernias form over time due to forces overstretching the tissue. Areas of acquired weakness can include previous surgical sites, which of course is the incisional hernia.

So hernias have numerous causes but are always

caused by a combination of pressure and an opening or weakness in the muscle or connective tissue, and it occurs where the pressure pushes through an organ or tissue through the opening. These areas can be weak from birth, from prior surgery, or from injury and aging. And anything that increases the pressure on this weakness, be it obesity, exertion, coughing and vomiting, can cause a hernia. Also lifestyle choices such as poor nutrition, tobacco use and overexertion can increase the likelihood of a hernia.

The common symptoms that bring people into the hospital for a hernia is generally the characteristic bulge that may or may not flatten or be reducible, pain that can range from intermittent discomfort all the way to extreme and persistent, a feeling of pressure in the abdomen, or constipation, blood in the stool or vomiting.

So next we will discuss the various treatment modalities. Because hernias are so prevalent, so are hernia repairs. It is reported that more than 1 million hernia repairs are performed in the United States each year, making it the second most often performed hernial procedure. And approximately 800,000 of the repairs are to inguinal hernias and the rest are to other kinds of hernias, to answer your Honor's question.

For some hernias nonsurgical approaches are an option. One nonsurgical approach is what they call watchful

waiting, where the physician will simply monitor the defect to ensure that it isn't causing any problems. And a second nonsurgical approach is a girdle, which as you can see can be used for either a ventral hernia or a groin hernia. As evidenced by the surgical intervention, these approaches were not appropriate for the plaintiffs here.

A traditional surgical approach is the non-mesh tension repair, which I believe Attorney Orent also refers to as the primary repair. This technique utilizes the patient's tissue to close the defect by suturing the tissue and muscles together to repair the hernia. The surgeon makes an incision over the hernia site, here, directly over the hernia site, and pushes the contents of the defect back into its correct anatomical position and then stitches the incision closed with the layers of muscle and tissue.

Because you need good tissue for this repair which has to necessarily be wider than the defect, this technique can cause a lot of tension leading to pain and also restrict movement. Therefore, this technique has a higher recurrence rate. And studies today still note the higher recurrence rate of this tension repair and hence the prevalence of the mesh repair, which is next.

The polypropylene mesh was introduced in the late 1950s for hernia repair and since the 1980s there has been an increase in mesh-based repairs. By 2000 non-mesh repairs

represented less than 10 percent of groin hernia repairs.

The use of surgical mesh has become popular because it provides a tension-free repair where the mesh, as opposed to the patient's tissue and muscle, acts as a scaffolding to reinforce the defect with the formation of scar tissue and is therefore associated with a decreased recurrence rate.

So as discussed a bit previously, mesh can be distinguished by the type of base material. There's polypropylene, polyester, and ePTFE or Teflon, and there's also biological or animal tissue.

The biological mesh is often used when synthetic mesh is not advisable where there is or has been a previous infection. Biological mesh is absorbable and not as strong as synthetic mesh, and therefore can be also associated with a higher occurrence rate.

JUDGE TEMPLE: Is there any breakdown in terms of the percentages that are used, whether it be -- well, let's just talk about the synthetic. In terms of those three products, is there a percentage for all surgeries performed in terms of what product is used?

MS. AYTCH: I'm not aware of the exact percentages. As Attorney Matthews mentioned, the polypropylene is a very prevalent one, but there are also the combination meshes that will use different kind of bases in order to achieve what they need to achieve depending on the defect, where it is,

and how it will be placed.

JUDGE TEMPLE: How often are the biological or animal tissue used?

MS. AYTCH: Those are not used as often. First, they are extremely expensive, and so they're not usually a hospital or a doctor's go-to. Second, it's absorbable, so it's not a permanent repair. Over time that will absorb, and so there is a recurrence rate. And thirdly, it's not as strong. So although I can't give you the exact percentages, your Honor, it is not as prevalent as the synthetic mesh.

JUDGE TEMPLE: Thank you.

MS. AYTCH: So there are two primary categories of surgical repair, which are open repair and laparoscopic repair. With an open repair the surgeon makes an incision near the hernia, and with the laparoscopic repair the surgeon makes several small incisions that allow for the surgical tools in the opening to repair the hernia. And I believe we've seen a number of videos showing the laparoscopic repair so we'll move beyond that.

In either an open or a laparoscopic repair the mesh must be secured by some fixation device, either sutures, staples, clips and/or tacks, and these devices can be permanent or absorbable.

Obtaining an adequate fixation is critical to a successful repair because the mesh must stay in place in

order to incorporate and provide the necessary scaffolding. And for this reason it is the defendant's position that a key indication of an inadequate fixation technique is the mesh migration or the balling up of the mesh. If it's not properly affixed all around it can come up, ball up and/or migrate.

Also critical to successful repairs is the physician's mesh selection, which requires consideration of the location and size of the hernia. As you saw, there are some meshes that are quite large. Also the surgical technique, patient specific considerations, such as whether or not there's an active infection -- to your question, Judge Temple, that is when a biological mesh would be used -- and the placement of the mesh.

And so the mesh placements were gone through with a bit of detail by Attorney Orent, so I'm just going to move through them fairly quickly.

So the four particular placements for the mesh are the onlay, the inlay, the sublay, or the underlay or the IPOM. As noted, the onlay places the mesh on top of the defect and muscle and close to the skin. So if we recall the abdominal wall, from an onlay when you're going -- making an incision and cutting down, you have to cut through the skin, the fat, the peritoneum -- I'm sorry, not the peritoneum -- the skin, the fat, and this layer of muscle in order to get

to the defect. On a larger person that can be a significant incision.

Some of the advantages of an onlay is that it avoids contact with the bowel and imparts less tension than in a non-mesh repair. But as discussed, some of the disadvantages are the high recurrence rate, and there is still some tension repair aspect and it requires wide tissue undermining.

The inlay places the mesh inside of the hernia defect and secures the mesh circumferally to the edges of the fascia. So in this representation which we've seen before, the red here is the muscle, the green is the mesh, the black are the little sutures, and here is the defect where it's being repaired.

So the advantages to this repair is that there is less chance of erosion and then it's technically an easier repair, but the disadvantage is that you're suturing to the edge of the defect here. And so again, you have to go to get good and healthy tissue, and that can involve suturing in attenuated and abnormal tissue which isn't the best place. Because of that, you also get a higher recurrence rate with this procedure.

Then we have the pre-peritoneal underlay, or otherwise known as the sublay method, which places the mesh under the defect and under the muscle but above the

peritoneum. So we're muscle, we're under it, but we're still above the peritoneum, which is down here. This placement allows for ingrowth from two different directions and has a lower recurrence rate because the intra-abdominal pressures from the muscle and the fat and everything are not pushing up on the repair because the repair is down here. However, this is often considered a more difficult procedure with greater risk of damage to the muscles and nerves because of where you're cutting.

And then lastly is the intraperitoneal onlay mesh, or the IPOM, which places the mesh in the intraperitoneal space on the peritoneum under the defect.

Intraperitoneal space, here we have the peritoneum, and we have the green mesh that is placed under it.

This repair, as was noted by the plaintiffs, was popularized by the laparoscopic technique. And because the mesh would be coming into direct contact with the peritoneum, a coated mesh is required. And the advantages and disadvantages of this procedure are the same as those in a laparoscopic repair because, as noted previously, this repair is done laparoscopically.

So there are many different ways to address hernia repairs. There is no magic method, as has been seen. As technology progresses and innovation furthers, the products on the market also have to evolve with the different

techniques.

This concludes my portion, and I will now turn over the presentation to my partner, Rebecca Ocariz, who will discuss the remaining topics beginning with the history of C-Qur mesh.

JUDGE TEMPLE: Can I ask you a question?

MS. AYTCH: Of course.

JUDGE TEMPLE: The coat you just talked about for the intra-peri -- however you say the word.

MS. AYTCH: Intraperitoneal?

JUDGE TEMPLE: Intraperitoneal. Thank you. I would butcher it in my New Hampshire accent so no one would know what I was talking about.

How many different coats are there?

MS. AYTCH: How many different --

JUDGE TEMPLE: Coats.

MS. AYTCH: Like the different types of products on the market?

JUDGE TEMPLE: In terms of -- we've heard about fish oil.

MS. AYTCH: Correct.

JUDGE TEMPLE: Am I understanding this right, that there is a coat that's placed on the mesh?

MS. AYTCH: Correct.

JUDGE TEMPLE: Is that the only product or are

there multiple types of coats?

MS. AYTCH: So there are multiple types of coats. The only coating that is at issue in these groups of cases, C-Qur mesh, is the Omega 3 fatty acids, but there are different types of coating with a number of different products. I believe the plaintiffs mention that Atrium, though, is the only one that has a product out on the market with the Omega 3 fatty acid coating.

JUDGE TEMPLE: Thank you.

MS. AYTCH: Thank you.

MS. OCARIZ: Good morning.

JUDGE MCCAFFERTY: Good morning.

JUDGE TEMPLE: Good morning.

MS. OCARIZ: A discussion of the history of C-Qur mesh needs to start with talking about the mesh design dilemma.

The mesh design dilemma is trying to balance a strong repair as against biocompatibility. Biocompatibility is the ability of a medical device to co-exist with living tissue or organisms without causing harm.

Every medical device implanted in the body will elicit a foreign body reaction. When hernia mesh was first introduced, initially the thought was that the mesh should be very strong and induce the greatest formation of scar tissue which would result in the strongest repair. What was

discovered, though, is unfortunately this led to pain and movement restriction in the patients who had this type of very strong mesh.

As hernia mesh devices have evolved, the focus has been on trying to find the ultimate balance between maintaining the strength of the repair and ensuring the biocompatibility of the device. C-Qur mesh was developed to provide a more natural healing experience with less tissue attachment and to reduce the inflammatory period of wound healing process to promote more rapid healing.

So what is C-Qur mesh? And you've heard a little bit about that today in that what C-Qur mesh is, is it combines Atrium's ProLite polypropylene mesh with an all-natural Omega 3 gel coating, which we've heard referred to as the 03FA. In certain placements the absorbable coating serves as a barrier between the polypropylene mesh and the internal organs.

Polypropylene mesh has been safely and effectively used for hernia repair since the 1960s. The base mesh in C-Qur is Atrium ProLite, which is a monofilament polypropylene mesh. ProLite is designed to facilitate faster tissue integration and a more normal healing response. ProLite has been on the market for 20 years -- for over 20 years, since 1994.

Importantly, ProLite has not been the subject of

any type of mass tort litigation, and I don't believe that any of the plaintiffs' firms that have filed C-Qur litigation lawsuits have filed any suits alleging that there's a product liability issue with ProLite.

So defendant's position is that there really doesn't seem to be any real issue with the ProLite mesh, which is the base mesh in the C-Qur.

The Omega 3 gel coating in C-Qur is derived from a highly purified pharmaceutical grade fish oil consisting of a unique blend of triglycerides and Omega 3 fatty acids. The fatty acids are familiar, naturally-occurring biological components that are commonly found in the human body. The liquid fish oil is transformed into a stable, absorbable gel coating through a thermal crosslinking process that you heard a little bit about today.

It was necessary for Atrium to transform the liquid fish oil into a semisolid gel because if the oil was left in its liquid form it would be absorbed by the body too quickly. Additionally, as a practical matter, it simply wouldn't work if the oil was coated in a liquid form on top of the mesh because the liquid would not adequately adhere to the mesh. So there needed to be some process implemented to convert the fish oil to the semisolid gel.

In this conversion process there are no chemical agents used to convert the oil into the gel, and this is an

important point because chemical crosslinking agents can cause hypersensitivity or a potential allergic response in select patients.

Additionally, the 03FA coating is nonallergenic and contains no heavy metals or proteins.

The Omega 3 fatty acid fish oil as a viscous liquid coating was first used on coronary stents in around 2001-2002, and the coating technology showed promise for other applications. So in 2003 Atrium initiated a research and development effort to develop the Omega 3 technology for use on a broad range of medical devices.

The Omega 3 fatty acid coating reduces the inflammatory response that occurs during the wound healing process allowing the lightweight mesh construction to heal rapidly with the new tissue. So again, you're seeing the attempt to balance the tension between ensuring a strong repair for the hernia so that you don't have a recurrence of the hernia and that the organs which were outside the body are returned to their proper anatomical place, and balancing that with a device that is as biocompatible as possible in order to attempt to minimize some of the adverse reactions which may occur which you have heard a little bit about today.

When a medical device is implanted in a body, any medical device, a knee, a hip, or mesh, the body elicits a

cascade of responses. In hernia repair the mesh device is used to replace the function of natural tissue that was lost due to the hernial defect. The tissue surrounding the implanted mesh goes through a process called wound healing. There are several different stages of the wound healing process that are automatically triggered by the tissue injury caused by the implantation.

The first phase is inflammation. This phase begins at the time of the implant procedure and lasts for a few days. Within hours of the surgical procedure the wound and the device are heavily populated with inflammatory cells, and during this phase of healing the wound strength is negligible.

The next stage of wound healing is proliferation, and here's where the body tries to close the wound area and create a new framework for blood vessel growth, and I believe Mr. Orent spoke about that process in some detail. This phase occurs from a few days to a few weeks post-procedure.

The last phase is the remodeling phase, and that occurs weeks after the initial implant procedure and lasts for months. During this phase collagen is deposited in and around the mesh material and it helps to strengthen the repair and helps to develop tissue that helps to serve the same purpose as the original tissue.

If the stages of wound healing are prolonged, the

patient is more susceptible to complication. So it's important to go from one stage to another as efficiently as possible.

And again, the 03FA coating reduces the inflammatory response that occurs during the wound healing process, and this is beneficial because the final stage and the smooth muscle cell healing and replication can't occur until the inflammatory phase is completed.

So you heard a little bit about C-Qur and you got the opportunity to look and touch some of the samples. So in the C-Qur device the entire ProLite base mesh is coated with the 03FA coating, but each side receives a different concentration of the coating. And so there are two sides to the mesh, and I think that you saw that, the smooth side and the rough side.

So the rough side has a thin uniform coating with an easily distinguishable textured finish, and this side is the side that is designed for the tissue incorporation.

The smooth side of the mesh, which has more coating on it, is suitable for placement along the organs. And again, the point of the barrier mesh and these types of coatings are to protect the organs from direct contact with the polypropylene.

And then this 03FA barrier stays in place while a new peritoneum is formed over the mesh. The 03FA coating

minimizes the formation of adhesions, and adhesions are -- as you've heard, they're scar-like tissue and they cause tissues and organs to stick together where they naturally wouldn't.

Ms. Aytch showed the short video about how much movement is going on in your abdominal cavity. And so imagine where those organs which are typically covered with a slippery substance so that they can expand and contract with pressure and with digestion, if adhesions are formed they tend to -- well, they bind the tissue and the organs together, which obviously interferes with the natural process of digestion and other types of movements.

So we also brought a few samples of the C-Qur mesh, but I think that you've had plenty of opportunity to see for yourself the two different sides of the mesh and how it works.

But what I do want to point out to you is that the mesh is delivered in this cardboard pouch, and then in the surgical procedure what happens is the circulating nurse who is outside of the sterile surgical field would open the cardboard container and would put the mesh -- would place the sterile pouch inside the sterile field. And then when the surgeon was ready to implant the mesh, then a scrub tech or a scrub nurse would then open this sterile pouch and remove the mesh.

So returning to how C-Qur works. The coating

contains familiar and naturally-occurring lipid components, as I mentioned before, that are commonly found in the human body and they are broken down naturally by the body. Typically the coating is absorbed within 90 to 120 days for the majority of the C-Qur meshes.

Preclinical studies demonstrated that the low temperature heat cured coating is completely absorbed by local tissue over time leaving the polypropylene mesh incorporated with fully remodeled, well-healed tissue. While the typical absorption rate is 90 to 120 days, the actual absorption rate will vary depending on the individual patient and their metabolism, but the preclinical studies demonstrated complete absorption within 120 days.

So C-Qur mesh was cleared to market by the FDA through the 510(k) process, and you've heard a little bit about that.

The mesh was made available to surgeons as a medical device through this process. And this is a premarket submission that's made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, or also known as substantially equivalent, to a legally marketed device. That statement that appears on the slide comes directly from the FDA website.

Moving on to the types of C-Qur mesh. Obviously as you've heard today, there are several kinds of C-Qur mesh and

they're designed for different sized hernias and different types of hernia repairs. The various models that I will discuss today are all at issue in the MDL and the state court proceedings.

The first is the C-Qur mesh. It was cleared to market in March 2006. It's a flat sheet mesh, and it's designed for open and laparoscopic hernia repair when a tissue separating layer is needed. So the C-Qur mesh is one of these barrier meshes that we were talking about which would be appropriate to place directly against organs.

The C-Qur mesh is available in a variety of sizes, all the way up to 12 by 18 inches, which would be a mesh for an extremely large defect.

JUDGE TEMPLE: And you agree that that type of mesh can be cut to size?

MS. OCARIZ: That is correct. Yes, this flat sheet mesh can be cut to size.

The mesh also comes in smaller sizes. And so just as a practical matter, it just wouldn't make sense for a surgeon to take such a large piece of mesh to cut it smaller because the more material that is purchased, the more expensive it is. However, if that is all that was on the shelf at the hospital, yes, the surgeon could take that. It's a single use so you can't keep the rest of it for safe keeping for later, but yes, you could cut it to size.

The next mesh in the C-Qur portfolio that's at issue is C-Qur Edge, and we heard a little bit about this. You can see that around the edge of the mesh there's a second layer of ProLite mesh, and that's around the perimeter of the mesh to ensure greater fixation and stability.

The C-Qur Edge also has a greater concentration of the 03FA coating. And like the C-Qur mesh, this mesh is also designed for open and laparoscopic hernia repair when a tissue separating layer is needed.

The next mesh in the C-Qur portfolio is FX. This was initially cleared to market via 510(k) on March 8, 2007. The FX product line has a light coating, they call it a light spray, of 03FA. This is designed for open and laparoscopic hernia repair when a tissue separating layer is not needed. So put differently, FX is not designed to be placed directly against the organs.

So as it indicates on the slide, this is not a barrier mesh, and so this is not appropriate for IPOM placement. FX is also available in various sizes and shapes.

V-Patch was initially cleared to market via 510(k) on April 16, 2008. The V-Patch is a round, double layer patch with a mesh stabilizing ring and two extended fixation straps.

This V-Patch is designed for the repair of small hernias such as umbilical, epigastric, and we talked about

how in laparoscopic procedures that you make small incisions. Those are to insert the instruments, some of which are trocars, and so the V-Patch could be used to repair trocar site defects and other abdominal wall defects.

TacShield was cleared to market on January 26, 2010. It comes in round, oval and oblong shapes. It is a C-Qur mesh with a second layer of secure FX around the perimeter, and you can see that it's kind of darker around there. That is a second layer of mesh. And again, that is designed for fixation and ease of handling during surgical repair of medium to large size open ventral hernias. So you would use TacShield when you have a large ventral hernia or a medium-sized ventral hernia and you're going to do an open repair, not a laparoscopic repair.

CentriFX was cleared to market on February 15, 2011. This was designed for a laparoscopic inguinal hernia repair. And again, because it has this FX designation it is not a barrier mesh, and so you would not use it in a placement that would require the mesh to be against the organs.

And the last product in the C-Qur portfolio is Mosaic. Mosaic was cleared to market via 510(k) on April 26, 2012. Mosaic is a flat sheet mesh designed for open and laparoscopic hernia repair when a tissue separating layer is needed. So this is one of the barrier mesh products that you

can put up against the organs. Mosaic has the lowest 03FA density coating of the C-Qur barrier meshes. And with Mosaic, the coating is typically absorbed within about 3 to 4 months.

This is a slide that indicates the percentage of each C-Qur product that is at issue in the MDL and state court actions. And in looking at this chart it's important to note that some of the plaintiffs had multiple hernias and were implanted with more than one type of C-Qur product. But what we see here is that the majority of the cases in both the -- in the MDL and the state court proceedings combined that we are aware of at this point are the C-Qur V-Patch. And that was the little, small disk type product that had the two fixation straps extending. Again, it was designed for the repair of small hernias.

And Judge Temple, I believe that you had asked whether there were more open procedures versus laparoscopic. So at least within this litigation the V-Patch is designed for an open procedure, not laparoscopic. So we would expect that in the 40 percent of these V-Patch cases that those would be open procedures.

So V-Patch represents 40 percent of the products at issue in the MDL and the state court proceedings but is followed closely by the regular C-Qur mesh and that represents 39 percent of the products.

That's followed by TacShield, which we just discussed. That is the product that has that extra layer of ProLite around the edge, and it's designed to address medium to large size open ventral hernias. And TacShield is at issue in 13 percent of the cases.

And then finally C-Qur Edge, Mosaic, and CentriFX represent 3 percent, 3 percent, and 2 percent respectively of the cases in the MDL and the state court actions combined.

These numbers were compiled on Monday, and as of Monday no cases involving C-Qur FX had been filed. However, this week after we compiled these numbers a plaintiff filed a case involving an FX device so that is not captured in this slide, but because it is only a single case, that represents less than one percent of the cases that have been filed thus far.

So as of today there have been cases filed involving each device in the C-Qur portfolio.

Moving on to complications encountered in hernia repair. As with all surgical procedures, some of the patients undergoing hernia repair will experience complications. There are risks associated with every medical device implantation. The patient needs to determine in conjunction with their physician whether the benefits of repairing the hernia outweigh the risks associated with the procedure.

The most common complications for surgical hernia repair with or without the use of mesh in the repair are infection, pain, adhesions, hernia recurrence, bowel obstruction, seroma, bleeding, fistula, and perforation. This particular information, again, that was taken directly from the FDA website based on what the website indicates was a review of peer-reviewed literature and other publicly available information.

All of these complications are well-known to the medical community and to surgeons performing hernia repair procedures. And not surprisingly, the most common adverse events alleged by plaintiffs in the MDL and the state court proceedings are these same adverse events well-known to the medical community. So I'm going to discuss some of these complications in greater detail.

You've heard a little bit about infection, but kind of starting at the basics, some of the plaintiffs in the MDL and the state court proceedings have alleged that they've experienced infections or abscesses, but not all. An infection is an invasion and multiplication of microorganisms referred to as germs or bugs such as bacteria, fungi or viruses.

An abscess is essentially a collection of pus that has been built up within the tissue of the body, and abscesses are generally caused by a bacterial infection.

There are countless types of bugs in and on the human body. All surgical wounds will become contaminated with bacteria during surgery, but not all wounds will become infected. And that's because most patients' host defenses are capable of controlling and eliminating the offending organisms when the bacterial contaminants are not overwhelmingly destructive or aggressive. Again, all surgical procedures have an associated risk of infection regardless of the area of the body or the use of an implant. The common denominator in these procedures is that they all require a skin incision which introduces a risk for infection.

A typical adverse event associated with surgery is a surgical site infection, or SSI. A surgical site infection is an infection that occurs after surgery in the part of the body where the surgery took place. In the United States there are approximately 2 million surgical site infections annually. The primary source for these infections for most surgical site infections is the patient's own microorganisms, and the most common organisms associated with surgical site infections are those naturally found on the patient's skin.

There are some people who have a history of diabetes or chronic obstructive pulmonary disease, also known as COPD, or other chronic illnesses. They tend to be more heavily colonized with bacteria. Infections can also be acquired from other patients, hospital staff, and

contaminated objects.

So half of the almost 2 million of SSIs that occur each year are associated with implantable devices. Bacteria adhere to the structural matrix of any implanted device by creating a microenvironment called a biofilm, and different devices generally and different mesh devices specifically have differing abilities to withstand biofilm formation with monofilament polypropylene constructing being a relatively resistant type of device to a biofilm.

Atrium conducted some in-vitro testing that showed that C-Qur mesh would not accentuate biofilm formation and showed that C-Qur behaved similarly with respect to biofilms with respect to many other competitor products.

One important point to keep note of when talking about mesh infection, and that might be a term that you hear throughout the course of this litigation, and that is that the mesh itself is not the source of the infection. The mesh has become contaminated by some type of a bug and an infection has developed in and around the mesh.

As I mentioned before, the mesh comes first in the cardboard envelope, then in this sterile pouch, and remains in the pouch until it is opened in the sterile field and then implanted in the patient.

So there are several surgical factors that can increase a patient's susceptibility and risk of acquiring a

surgical site infection, and those include the duration of operation. The longer the procedure, the greater the risk of infection. Generally stated, if a hernia repair procedure lasts more than two hours, that puts the patient at a higher risk of developing an infection. Also, whether you have an open procedure or a laparoscopic procedure. An open procedure involves a much larger incision as opposed to the smaller incisions that are made for the laparoscopic equipment, and so an open procedure has a higher rate or risk for infection.

The placement of the mesh also matters in terms of the relevant risk associated for an infection. We spent a lot of time today over the four various placements of the mesh, and if the mesh is placed closer to the skin there's actually a higher rate of infection.

Another type of surgical issue that increases the risk of infection are the use of surgical drains. Some surgeons may elect to place a drain within the abdomen of a patient in an attempt to reduce the risk of post-operative seromas. We heard a little bit about seromas today and I'll go into it a little bit more later, but when you have a surgical drain it can also act as a highway for bacteria to travel from the outside of the body inside the body.

There are also several patient factors -- individual patient factors that affect a patient's

susceptibility to an infection. One of them is the American Society of Anesthesiologists score, the ASA score. That is a score from 1 to 5 that categorizes patients by their preoperative physical fitness level, and a score of 1 is a patient in normal health with 5 being a patient who's not likely to survive 24 hours. When a patient has an ASA score equal to or greater than a 3, that has been associated with a significant increase in surgical site infection after hernia repair.

Diabetes is also one of the major predictors of post-surgery infection and complications. As you likely know, diabetes is a systemic immunosuppressive disease associated with various conditions that have also been shown to have a devastating impact on wound healing and prognosis.

Obesity and body mass also play a role into the likelihood of an infection. A person with a body mass index, or BMI, greater or equal to 30 is considered to be obese, and some studies suggest that hernia patients with a BMI greater than 30 have twice the risk of developing an SSI following a hernia repair than patients with a BMI lower than 30.

Malnutrition and age are also factors that increase the risk for an infection.

Tobacco use. Smoking has been associated with inhibited wound healing and decreased circulation.

Preexisting and previous infection, steroids and

immunosuppressants, medications that in any way compromise or alter the body's immune response affect the body's ability to fight off and defend against an infecting agent.

And then finally, any type of immunosuppressive condition, such as HIV or AIDS, or if the patient is undergoing chemotherapy, these are also examples of patient factors that affect a patient's susceptibility to infection.

Not surprisingly, the plaintiffs in the MDL and state court proceedings present with some risk factors for infection. For example, in the MDL 58 plaintiffs have served plaintiff profile forms, and this provides more information than the general information that's provided in the short form complaints.

Because we're pretty much at the beginning stages of the filings in the MDL and some of the information is somewhat limited in the state court proceedings, right now we have information as to 58 plaintiffs out of the 186 plaintiffs that we were aware of as of Monday.

So for example, plaintiffs in the MDL and state court proceedings of these plaintiffs who have reported, 60 percent of them are smokers. 31 percent of these plaintiffs are obese. 21 percent of these plaintiffs have diabetes. So in sum, really the take-away here is that there are a multitude of factors that affect an individual patient's likelihood of experiencing an infection after a surgical

procedure.

Moving on to abdominal adhesions. Adhesions can cause tissues and organs in the abdominal cavity to stick together. Adhesions can cause pain or intestinal obstruction.

There are reports that 93 percent of patients who undergo abdominal surgery develop abdominal adhesions. There's no hernia mesh device that prevents the formation of all adhesions. However, C-Qur did a study and it's clinically demonstrated that C-Qur has less tenacious tissue attachment than competitors, tenacious meaning they're clinging tightly to the organs, so the adhesions are easier to take down. I believe Mr. Matthews went through the various degrees of strength that an adhesion may have.

JUDGE MCCAFFERTY: So tenacity and density would be synonymous.

MS. OCARIZ: Tenacity is a term that's used with adhesions. You will see in the literature references to tenacious adhesions, and that just means in that context that it's there, it's on tight. It's not a loose attachment.

Density I think is another concept.

JUDGE MCCAFFERTY: Okay. And I think in their list of adverse reactions dense adhesions was listed under problems caused by the C-Qur mesh.

MS. OCARIZ: That's right. And that's certainly

going to be an issue in this litigation, because I think that the parties have different views on how C-Qur works and the type of adhesions that occur when using this mesh.

JUDGE MCCAFFERTY: Okay. But density would be a different thing than tenacity.

MS. OCARIZ: I'm actually not familiar with the term of density adhesions. I think the way that it's being used is probably used in the same context as tenacity. So basically the plaintiffs' position is that the adhesions are more tenacious, and we're taking the position that the adhesions are not.

JUDGE MCCAFFERTY: Okay. Let me ask you also just about infection, because infection is a common adverse reaction to these -- the hernia repair.

But in the plaintiffs' list they listed chronic infection, and I'm wondering, chronic would mean obviously somebody who has repeated infections as a result of the product?

MS. OCARIZ: So chronic is something that has developed over time as opposed to something that is acute which develops almost immediately or quickly.

It is Atrium's position that with respect to all of these adverse reactions, that the rate of the adverse reaction that has occurred with patients undergoing a hernia repair using C-Qur is no greater than, and in some instances

less than, other similar hernia repairs using different mesh products.

So again, I anticipate that this is going to be an issue of dispute between the parties.

JUDGE MCCAFFERTY: And meshoma is listed in their list as well as a side effect of C-Qur. That's not in -- it's not a common complication in your list.

MS. OCARIZ: So in a mesh repair one of the more common potential adverse that can occur is mesh migration and mesh shrinkage. So I believe the meshoma was referring to the potential for the mesh to contract and to ball up. So with a mesh repair that is one of the more common types of adverse events.

In these cases so far with what we have been able to track that is not as common as some of these other things that we are discussing. And it's also the defendant's position that proper surgical technique and proper fixation is critical to aid against mesh migration or mesh contraction. And the theory is that if the mesh is properly affixed, it's not moving, and so it's physically much more difficult for the mesh to contract. If it's properly affixed, I don't want to say it can never ball up, but it can't ball up because it's lying flat in its proper location.

And that's why Ms. Aytch talked about the importance of fixation and proper surgical technique to make

sure that the mesh is in the right place and it's there until you have the opportunity to get this adequate tissue ingrowth, which then provides the strength of the repair and keeps the organ in its proper anatomical position inside the abdominal cavity.

JUDGE MCCAFFERTY: How about skin rash, is that something unique to the C-Qur product?

MS. OCARIZ: Actually, there have not been many reports of skin rashes in the cases that have been filed based on the information we have thus far. Skin rashes are not unique to C-Qur. There have been reports of skin rashes with other polypropylene type of mesh products.

As I mentioned before, the coating itself is a highly purified pharmaceutical grade fish oil and it is removed of proteins and other type of allergens which are typically the type of components that would cause an allergic reaction.

So I hope that that answers your question.

JUDGE MCCAFFERTY: Yes.

MS. OCARIZ: There are also a number of things in the surgical suite that could cause an allergic reaction. There's an antiseptic called Betadine. As an anecdotal report, we have heard of at least one case where the surgeon decided to take the mesh, to dip the whole mesh in Betadine, which is an antiseptic, I guess under the thought that that

would help decrease infection because, you know, if it's completely dipped in an antiseptic, then the thought was, you know, the infection will not -- there's a lower chance for infection.

However, some people have reactions to Betadine. And so when you dip the entire mesh, which is not called for in the surgical protocol to apply any Betadine to the mesh, and then it's implanted inside you, some people have experienced an issue with that.

There are also other agents in the surgical suite. Iodine, latex, antibiotics, all of those things can contribute or can exacerbate a rash.

With bowel obstruction, as the name suggests, it's a blockage in the bowel and the contents of the intestines cannot pass through and exit the body. Bowel obstructions can be caused by adhesions, which are those tissue attachments of -- abnormal tissue attachments between tissue to organ or organ to organ, which as previously mentioned has been reported to occur in 93 percent of all abdominal surgeries.

With seroma -- so seroma is a pocket of fluid that sometimes develops after surgery, especially in procedures that are extensive or involve significant tissue disruption. And so seroma formation happens because the body is reacting to a vacant space within the tissue.

There are some papers that contend that a hundred percent of hernia patients develop seromas. The seromas can either resolve on their own, or other times they need to be treated with either a surgical drain or they need to be otherwise procedurally handled.

So returning again to the slide showing the most common complications arising from hernia repair with or without mesh, again, with respect to the rates of occurrence for these adverse events associated with C-Qur, Atrium found, and it's the defendant's position, that the rates of occurrence with these known complications with C-Qur products was no greater than reported complication rates associated with other hernia repairs.

So I thank you for providing us with the opportunity to present on these issues. I'm available for any additional questions. Otherwise, I know that Ms. Aytch has some procedural issues that she needs to address with the Court.

JUDGE TEMPLE: Thank you.

JUDGE MCCAFFERTY: Can I ask a few questions? You mentioned that there were preclinical studies. Do you do those as a company, because it looks as though -- are those required somehow or is that just an internal?

MS. OCARIZ: Those were done before the product goes to market, and it's my understanding that they were done

at the behest of the FDA or at least to facilitate the process.

JUDGE MCCAFFERTY: Okay. And so preclinical studies, do those happen with each product; do you know?

MS. OCARIZ: They happened with the initial C-Qur product, and then I know that they happened before the launch of some of the other products. If this is something that the Court is interested in --

JUDGE MCCAFFERTY: I just was curious because you had mentioned that there were preclinical studies done, so I was curious because the process of FDA approval as described by I think primarily Attorney Orent described just the process of confirming that the newer product is substantially similar to the previous product.

MS. OCARIZ: Right. There's a lot of latitude that the FDA has in requiring what a manufacturer has to do before the FDA will clear a product for sale and make it available on the market. And so the FDA can require some type of studies.

Mr. Orent is correct that typically those studies are in vitro, meaning that they're either in a petri dish -- they're not in a human.

The preclinical studies that Atrium did, two of them were small animal studies, which I believe were done with rats, and one was a rabbit study.

JUDGE MCCAFFERTY: Okay. And one of the C-Qur products involved the fish oil covering the pores completely. Which product is that? Is that the FX?

MS. OCARIZ: No. So any of the products with the FX, that has the light spray of the coating.

JUDGE MCCAFFERTY: Okay.

MS. OCARIZ: So that has a much lighter spray. Any product that is a barrier mesh will have a thicker coating and that was the thick size, and it's designed that way to be a barrier between the polypropylene mesh and the organs.

JUDGE MCCAFFERTY: Okay.

MS. OCARIZ: But what happens with this -- so you don't want ingrowth on that. What you want to have happen is you want it to be absorbed and the new peritoneum will be formed over it.

JUDGE MCCAFFERTY: Okay. But some -- the Mosaic is a newer design which does have the force, right?

MS. OCARIZ: Yes. So what Mosaic is, is it has a lighter concentration of the 03FA coating and it also -- it doesn't cover every single pore. Again, the studies that Atrium did on the C-Qur found that, let me see, that -- again, the coating is fully absorbed over time leaving the polypropylene mesh incorporated with fully remodeled tissue. So again, I think that this is a point of dispute between the parties as to how the mesh actually performs.

JUDGE MCCAFFERTY: Okay.

JUDGE TEMPLE: Do you agree with Attorney Matthews in terms of the basic scientific issues that are presented in the case? And you can correct me if I'm wrong, but I think some of the ones he mentioned were, for instance, sterilization combined with fish oil issues, the smooth versus rough side in terms of tissue not being able to get into the mesh, the tack issue, and then we got on to sort of the -- what you've been talking about recently, these complications and whether the instructions and warnings are enough, and I think you also mentioned degradation of the polypropylene.

MS. OCARIZ: So some of what Mr. Matthews shared today is newer information for us, but I think that it's safe to say that any of the positions that the plaintiffs have set forth today about how the mesh reacts to the extent that it causes an increase in the rate of infection or causes any type of an increased rate of adverse complications unlike any other types of products on the market, that is certainly an issue that we will deal with and that is something that the defendants have a different take on.

JUDGE MCCAFFERTY: Thank you.

JUDGE TEMPLE: Thank you very much.

JUDGE MCCAFFERTY: Attorney Aytch.

JUDGE TEMPLE: Attorney Aytch.

MS. AYTCH: Thank you, your Honors. I'll only be one moment.

Your Honor, Judge McCafferty, during our monthly status conference in September, I believe on September 25th, when discussing science day, the Court welcomed the defendant, should a need arise, to re-raise the issue of confidentiality. And I would like to renew the request that a portion, not all of today's presentation, but a small portion of Attorney Matthew's presentation be either sealed or redacted. That portion deals with the interpretations of Atrium's design and manufacturing process, including the sources of the particular ingredients, which we contend is proprietary information that is not publicly known, that is confidential, and we would ask that those particular slides and that particular portion of the transcript be either redacted or sealed.

JUDGE MCCAFFERTY: All right. And this would be -- are you thinking we're talking about two pages of material? Can you recall specifically?

MS. AYTCH: I can identify them. I'm sorry, your Honor, I've not gone back through, but it would be like two to three slides, no more than four.

MR. JAMES MATTHEWS: Can I say something?

JUDGE MCCAFFERTY: Sure.

MR. JAMES MATTHEWS: The slides where I would click

and it would go to the next -- it would show the distributor and then it would show the maker of the polypropylene, and then it would show that it was being -- those two slides I think is what she's talking about.

MS. AYTCH: Correct, your Honor.

JUDGE MCCAFFERTY: Those two slides. And those two slides being removed would be sufficient for you, or would you want to also remove what he was saying to us?

MS. AYTCH: Correct. Because we contend that it actually discloses information that is not publicly available, and we wouldn't want it out in the public record.

JUDGE MCCAFFERTY: Do you have any problem with just sealing that small portion?

MR. JAMES MATTHEWS: No.

JUDGE MCCAFFERTY: Okay.

MR. JAMES MATTHEWS: And if I did that, it was inadvertent and I apologize. I believe we might disagree with that, but we don't have any problems sealing that or redacting that.

JUDGE MCCAFFERTY: Okay. I think you've given me enough information for me to feel comfortable that that small portion can be sealed.

In terms of process with respect to the transcript, before we make that transcript public in any way we'll obviously resolve this issue and have you notify us and our

stenographer of exactly what portion you want to be sealed before we put it on the website.

MS. AYTCH: Thank you, your Honor, and I'll share those portions with plaintiffs so they can have input into that.

JUDGE MCCAFFERTY: All right. Okay. Anything, Attorney Orent, Attorney Matthews?

MR. ORENT: Not from the plaintiffs, your Honor. I do believe those are slides 42 and 43 just for the record, but I can confirm that.

JUDGE MCCAFFERTY: Okay. Slides 42 and 43 then will be removed from that PowerPoint exhibit, and we will wait and then redact just a small portion from the actual transcript before we put that on the website.

Okay. Is there anything further?

MS. AYTCH: Thank you, your Honor.

JUDGE MCCAFFERTY: You're welcome.

Now for bellwether trials, I'm just curious, do you pick a certain sort of type of plaintiff, a plaintiff who would perhaps fall in that score category of a 1 or a 2, and maybe one of the two major products that are causing the litigation? Is that how you intend ultimately to settle on a bellwether, or have you not had discussions along those lines? I'm just curious.

MR. ORENT: Your Honor, we haven't had formal

discussions in terms of the actual method that we would use in this case. We've done it in several ways before. We've done it where we select some objective criteria and both the parties try and pick cases that work towards that criteria. And we've had situations where each side picks X number of cases and then we work them up and then have the Court narrow the pool from that perspective.

One of the things that we are doing is that we've been working with an online provider, essentially, that will allow us to send the fact sheets to the defendants through a secured hub, if you will, and it will allow both parties access to aggregated information on the docket so that we will have high-level information about the types of cases, the complications on the cases, so that should ease in the process, and I believe both parties have agreed to a single vendor for that. So it is something that we are working towards and we'll have that high level of information to be able to share with the Court to aid in the bellwether selection process.

JUDGE MCCAFFERTY: What was the percentage again, Attorney Ocariz, of plaintiffs in the litigation who smoke? Was it 60 percent? Did you say 60 percent?

MS. OCARIZ: Your Honor, I believe that, yes, smoking was 60 percent and then obesity and diabetes were around 30 or 20 percent. Again, this is based on very

limited information that's available to us. The best information we have right now are the plaintiff profile forms which provide a little bit more information than the complaint, but obviously as more time passes we'll be able to develop a more accurate profile of the plaintiff population.

JUDGE MCCAFFERTY: I was just thinking perhaps you wouldn't want the ideal plaintiff in the case, you would want to have a case that would be more indicative of sort of a more typical plaintiff so you can get a sense of how the case will ultimately come in with that kind of plaintiff.

MR. ORENT: Well, your Honor, I think it's important, and maybe it wasn't said during the science day presentation today, but the people who have hernia surgeries and require mesh devices generally are not the healthiest of people anyway. If obesity is a large factor, and perhaps one of the largest factors in ventral hernias, you're going to have a patient population that is tilted, and these devices were actually designed for people with each of these factors. And so this sort of goes into the population that was expected, at least in our view, to receive these devices in the first instance.

JUDGE TEMPLE: And in our selections I think for the first bellwether trial, and you can correct me if I'm wrong, I think are to have that trial begin in late August of next year, right?

MS. AYTCH: Your Honor, you had granted us a three-month extension, so I believe that that date is now November 2018.

JUDGE TEMPLE: Oh, it is. Okay, great. That's why I told you to correct me if I'm wrong.

MS. AYTCH: Thank you, your Honor.

JUDGE TEMPLE: I like the earlier dates better, but I'm used to this at this point so thank you, Attorney Aytch.

JUDGE MCCAFFERTY: I think we're properly enmeshed in the science.

JUDGE TEMPLE: Thank you very much.

JUDGE MCCAFFERTY: We appreciate it. Thank you.

JUDGE TEMPLE: It's been extremely helpful. Thank you.

(Conclusion of hearing at 12:25 p.m.)

C E R T I F I C A T E

I, Susan M. Bateman, do hereby certify that the foregoing transcript is a true and accurate transcription of the within proceedings, to the best of my knowledge, skill, ability and belief.

Submitted: 11-17-17

SUSAN M. BATEMAN, LCR, RPR, CRR
LICENSED COURT REPORTER, NO. 34
STATE OF NEW HAMPSHIRE

I, Susan M. Bateman, certify that the foregoing is a true and correct copy of this transcript incorporating redactions requested by the parties and approved by the Court in accordance with Judicial Conference policy. Redacted characters appear as a blank line on the paper copy and a black box on the electronic transcript

11-17-2017
DATED

SUSAN M. BATEMAN, LCR, RPR, CRR
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STATE OF NEW HAMPSHIRE