IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION,	Docket No. 11 C 5468
	Chicago, Illinois
	January 12, 2012
	2:08 p.m.

TRANSCRIPT OF PROCEEDINGS - Motions
BEFORE THE HONORABLE REBECCA R. PALLMEYER

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THE CLERK: 11 C 5468, Zimmer NexGen Knee Implant Product Liability for in-court hearing.

THE COURT: Good morning.

MR. RONCA: Good morning, your Honor.

Do you want general appearances?

THE COURT: Sure. Why don't we do that.

MR. RONCA: Jim Ronca for plaintiff steering committee.

MR. MILLROOD: Tobi Millrood for plaintiff steering committee.

MR. BECKER: Good morning, your Honor.

Tim Becker for plaintiff steering committee.

MR. FLOWERS: Good morning, your Honor.

Pete Flowers.

MR. YEAGER: Good morning, your Honor.

Jay Yeager for the defendants.

MS. PIERSON: Good morning, your Honor.

Andrea Pierson for the defendants.

You know my partner Kurt Stitcher, but I also want to introduce you to my partner Abigail Butler.

The Court may have noticed my increasing girth during these conferences.

THE COURT: I would never comment.

(Laughter.)

MS. PIERSON: I think it's unlikely that I will be

at the next couple of status conferences, but Ms. Butler will be here in my stead.

Ms. Butler and Ms. Sellers, who you met last time, also have been leading our efforts on the collection of documents. So she will be addressing that with the Court today and is in the best position to tell you about the efforts that have been ongoing since our last conference.

THE COURT: That's great. Okay. Good.

Well, we are ready for these presentations.

Let me tell you that I enjoyed reading your submissions and feel I know a bit more about the technology and the concerns that are generated by these knee implants, but I am looking forward to this live show.

MR. RONCA: Okay. And, your Honor, during the course, while I am speaking first here, I may have to sometimes turn my back to you a little bit, so I hope you don't mind.

THE COURT: That's fine. In fact -- I don't know how much light you need. Can I turn out the lights?

MR. RONCA: I don't need anything, your Honor.

THE COURT: At least for now, let me turn out -- let's make this scene more dramatic here, this space scene.

MR. RONCA: This is the universe -- no.

THE COURT: I know. I love starting here. Let's go back to the big bang.

MR. RONCA: Let's talk about knees, though, your Honor.

First, let me say that most people view the knee as a hinge joint, like a regular hinge, which moves in one plane of motion. The difference being that this hinge has mechanical connections which make it very, very stable.

The knee itself is really the meeting of two bones, the upper bone and lower bone, as you read in the papers, and it's connected by literally ropelike ligaments. That is what holds it together.

The difference, obviously, between the hinge and the ropelike is, the rope is flexible along its length, but it's of a fixed length and does not stretch. You will see how this becomes important as we discuss it.

So if we want to start, then, what we want to do, your Honor, is take -- please ignore the androgynous avatar here.

We want to start really bringing you down to the bone level and working outward on all the structures.

So the basic structures of the leg, as you know, are the femur, or thigh bone; the tibia, or shin bone; the patella, which is the kneecap; and the fibula, which is the small bone in the lower leg. It is not weight-bearing, but it connects to certain muscles that are used in the knee.

THE COURT: And we are looking at a right leg here?

MR. RONCA: That's a right leg. You can see --

If you will, freeze it, please.

So you can see the length of the femur. The top is the acetabulum, which fits into the hip. At the bottom where it widens is where the knee connects with the femoral condyles, which we will see in another slide as we go on.

So you can continue.

So this is a further close-up of the knee. It's showing you in rotation and the posterior.

Now, if you can, freeze it there for a second.

So in the posterior, you can see the tibia, the femur, and the fibula.

Now, a couple of guide points whenever you read medical things about the knee. So the medial -- I have a laser.

THE COURT: I am sorry. Once again, this is a right?

MR. RONCA: It's the same leg. It's always going to be the same leg in these animations.

THE COURT: And that's why the fibula is on the outside.

MR. RONCA: Right.

Whenever we refer to distal, what we are referring to is the part farthest away from the center of the body, or the lower part of the leg. But your head is also distal to

the center of the body. So distal means farthest away.

Proximal means closest. So this is the proximal part of the tibia, closer to the center of the body. This is the distal part of the femur, farther from the center of the body.

And then, there is medial and lateral. Medial is in the middle, or between the knees. Lateral is the outside where the fibula is.

So we are looking from the posterior, or back. Medicine always needs a word instead of the actual word.

THE COURT: Right.

MR. RONCA: Anterior is front.

So this will rotate now.

If you will, proceed.

And you can see, then, the bone structures from the other side of the various bones, and it will rotate around to the front.

Now, the next animation will show you a close-up view of the knee exploded and will identify the various articulating surfaces on the bony aspects of the knee.

So again, we are going to move the bones apart, move the patella out. And you will see these knoblike projections on the end of the femur. They are called the femoral condyles. Condyle means something that articulates.

In between, there is a patellar groove. The back

of the patella moves through this groove and articulates there.

And then, this is called tibial plateau. This is what supports the weight coming down through.

If you will, freeze it, please, for a second.

And it has two condyles also. They are sort of concave. They have bony eminences in the center, which provide attachments for the various cartilages.

And that's the basic bony anatomy.

Go to the next.

Now, there are two types of cartilage that are important to the knee: articulating cartilage and the cartilage in the menisci.

The articulating cartilage goes on the moving surfaces of the knee. So you are going to see that it's on the bottom of the condyles, it's on the tibial plateau, and it's also on the back of the patella.

And what happens is, the bone moves on these two types of cartilages.

Go to the next one, please.

The other type of cartilage are called the menisci. They are set there: the lateral, or outside; and the medial, or inside. The bone sits on top of that. These act as shock absorbers. So as opposed to being articulating surfaces on which the bones move, these are shock absorbers for shocks

when the load of the body is put on, especially, for example, when running. And they are more spongy and have different properties than the articulating cartilages.

Next slide.

Now, you can see how the bone moves on this articulating cartilage. And the importance of the cartilage in the bone is that it spreads and diffuses the pressure of the weight and makes it an even spread across the bony surface.

In addition -- and you will see in another slide -- the character of this particular articular cartilage is such that it is a very high lubricant. I think we characterized it as like water on ice. And it's so well lubricated that it can make these motions tens or hundreds of thousands of times in your lifetime and the knee will operate properly because very little friction is generated by the movement.

Next slide, please.

So this is a close-up.

If you would, freeze it for a second. I want to point a couple of things, although my thing doesn't seem to be working very well.

THE COURT: Is this cartilage on the top and the bottom of the -- is it a relatively consistent thickness?

MR. RONCA: Yes, throughout that surface.

So again looking at a model that I have here will

reflect that. It's, for our view, a thin surface --

THE COURT: Right.

MR. RONCA: -- on the articulating surfaces of the bone. And it's coating that. It is a thick matrix, rubbery-type substance. And I am going to explain in a minute how it uses fluid to create its nourishment and it's -- the slipperiness that enables it to glide one over the other.

THE COURT: To slide. All right.

MR. RONCA: So freeze here.

I just want to point out a couple of structures here.

So this is the cartilage matrix, articular cartilage, that forms on the surfaces of the bones that are in the joint (indicating). And there is cartilage like this in many joints. But it's very important in the knee joint because the weight of the body is all on the knees.

Now, it has a mechanical connection to the bone. Now, what you can hardly see there is that there is a layer of cortical bone. Bone has -- there's two types of bone, especially in the long bones of the body like the femur, which is the longest bone in the body.

Can you go to that slide of the -- I am getting ahead of ourselves here, but -- not that one. Go down two. There.

So when you have bone, you have this hard bone on the outside called cortical bone. It's smooth. And then the bone on the inside is called either trabecular or cancellous bone, and it's got a latticework, or like a honeycomb structure. It's very strong. You can't look upon it as being like a soft or spongy. It's spongy in appearance, but it's hard and strong, and it supports the inside.

All right. If we can, go back to the animation now, please.

So that's this bone here (indicating). This is the cancellous bone, which has -- and it's important because we will see, when we do a replacement, that it osseointegrates with the devices or with the cement, and that's what causes the attachment.

Now, this structure of the articular cartilage, it consists of proteins and cells. The cells are represented by these dots.

And there's two types of proteins. One is collagen, which you may have heard of, which is a connective tissue that's used throughout the body, and it's literally called a type of protein that holds the body together; and another one called proteoglycans. These are cells -- they are not cells. They are proteins that attract water, attract moisture, and attract nutrients into this matrix.

So you have long lines of the -- my battery is

dying. The white lines there are the collagen cells, which cause like a fibrous strength on the outside of the cartilage. The chondral cells -- chondral means cartilage. If you ever see c-h-o-n-d, that means cartilage. If you see cytes, that means cells. So these are chondrocytes or cartilage cells. They are the ones that organize these proteins. And the proteoglycans are inside.

And this matrix is permeable so that fluid can flow in and out.

Next slide.

So importantly, the bones have their own blood supply and nerve supply. The bones can feel pain. If you break a bone, that pain is coming directly from there.

On the other hand, the cartilage does not have a blood supply and does not have nerves. If you cut the cartilage, damage the cartilage, have arthritis in the cartilage, the cartilage itself does not generate pain.

The pain is generated by two things. One is pressure points on the bone.

If you will, freeze it for a second.

When the bone hits a pressure points -- in other words, remember I said about the spreading of the pressures, the spreading of the weight by the cartilage. When the bone gets pressure points, it reacts with pain to the nerve cells of that pressure point. So if you can think of like a

broad -- a shoe with a broad heel stepping on your toe versus a spiked heel, same weight, you get more pressure. And that pressure causes pain.

So it's important to get this even spreading. And if you don't get this even spreading, if there is roughness, if the cartilage is replaced with fibrous tissue because of scarring or for any reason you don't have the even spreading of the load on the knee, you get pain in the bone. And that is one of the mechanisms of pain.

Now, the cartilage -- you can proceed with the animation.

The cartilage receives its nutrients from surrounding fluid. All joints have a capsule around them.

If we can, go to the slide of the capsule, which is the first slide.

All joints have a capsule around them, and the capsule contains fluid. Inside the capsule is synovial tissue. If you can, picture tissue with a lot of blood vessels in it.

And then there is fluid flowing in between and all around the cartilage. And what happens is, this fluid absorbs nutrients and oxygen from the blood. And then that fluid, because of those proteoglycans that I mentioned, is absorbed into the porous matrix, and it supplies nutrition to the cartilage. And that's how the cartilage gets its

nutrition.

That cartilage that we talked about, that articular cartilage, is about 65 to 85 percent water. And you can understand, then, why it has that property. If you could, think of like a yoga mat, how that spreads pressure when you are doing whatever kneeling you might do in yoga or kneeling doing gardening on one of those pads. It spreads pressure because it has this water inside and it is almost like a waterbed in terms of the way it spreads pressure.

Now, a couple things can happen. When the cartilage starts breaking down, it stops absorbing the nutrients as well and then it ages. That's one thing that happens.

The other thing that can happen is, it can get too much water. It can break down in a way where it has so much water in it, where it has 90 percent water weight, that it doesn't spread the weight as well.

So really -- and what we are going to see is that arthritis in the knee is a breakdown of this cartilage. And what a knee replacement does is not replace the joint but replace the surfaces, the moving surfaces, of the joint, unlike a hip replacement where the whole joint is taken out. This does not replace the whole joint, just the surfaces.

THE COURT: You said "unlike a hip replacement."

MR. RONCA: Unlike.

THE COURT: I know this is kind of extraneous, but does that mean that the recovery time for a hip replacement is longer or not really?

MR. RONCA: I did not study that, but maybe Mr. Yeager knows the answer to that.

THE COURT: I have two natural knees and hips at this point, but who knows what the future holds.

MR. RONCA: I don't want to scare you.

Let's go back to the animation, which -- is that moving? Okay. Go back.

In any event, there is fluid -- if you start this one again.

Go to Slide No. 2, please. I just want to show the Judge one more picture.

So I mentioned these cells that are in the matrix. And this is a drawing of the matrix of articular cartilage at the top, the collagen fibers, the proteoglycans, and the chondrocytes, or cartilage cells.

Now, down on the bottom, that's a photograph. It's done in a laboratory so they use colors to emphasize different cells. You can see the different cells and the different shapes of the cartilage itself.

So that articulating cartilage is essential to the function of the knee.

Now, the other thing that's essential to the

function of the knee is ligaments.

If you go to the next animation, the ligaments are those ropelike structures that literally hold the knee together. Otherwise it would have no structural integrity at all.

So there are four main ligaments that hold it together. The lateral collateral and medial collateral ligaments are on the outside. Lateral being outside and medial, inside.

Freeze it, please.

Then, in the center -- so at the top we have the quadriceps muscle that we are all familiar with, our thigh muscle, in the front; the kneecap; and the patellar tendon.

Patellar tendon is an interesting structure for a couple of reasons.

First off, it's part tendon and part ligament. Remember I said that ligaments, which connect bone to bone, have a fixed length. Tendons do not. Tendons can stretch.

The patellar tendon is a unique combination of ligament and tendon. The part that connects the patella to the tibia, the kneecap to the shinbone, that's partly ligament, so partly doesn't stretch.

And what that does and why this bone evolved the way it did is, it's a hard surface within the tendon which creates a fulcrum so that you can get more leverage so you

can straighten out your knee easier.

So when you bend the knee, as we will demonstrate later, up to about 30 degrees, that patellar tendon stretches. But then after 30 degrees of bending, which isn't very much bending, it doesn't stretch any longer. So it becomes fixed, and that pulls the patella up above, as we will see in our rotational views.

Go ahead.

So this is the medial collateral ligament.

Now, each ligament -- stop it, please -- has two lengths. It has one length for flexion and one length for extension, both fixed.

So when you are totally in extension, your stability relies on the extension -- extension means straightening -- extension part of the tendon.

And when you are totally flexed, stability relies on the flexion part.

So each one has two attachments, each one has two lengths, and that's how the knee is held together from the outside.

Go ahead.

Quadriceps tightens, the leverage goes against the patella, pulls the leg straight.

Now, inside, there are two other ligaments that -- we have probably all heard of the ACL, or anterior cruciate

ligament, and the PCL, or posterior cruciate ligament.

Freeze it, please -- or go back a little bit.

The anterior called because its primary attachment to the tibia is in the front, or anterior, and then reflects up to the back and attaches to the femur. The posterior is attached pretty much in the posterior of both sides.

These ligaments also help hold it together, and they also help prevent the knee from sliding on itself forward and backward. So the anterior resists backward sliding and the posterior resists forward sliding.

They are called cruciate because they are cross, meaning -- cruciate meaning cross each other.

And what we are going to find out is, in replacement surgery the anterior cruciate ligament is always removed. In fact, you can live your whole life without the anterior cruciate ligament, but your knee will be a little loose in certain motions.

Posterior cruciate ligament is actually stronger and more important. And it is either kept in the replacement surgery or replaced with a post, as we will demonstrate later.

You can continue.

THE COURT: What attaches the ligaments to the bones?

MR. RONCA: If you can, stop for a second.

The ligaments have a mechanical attachment to the bone that is natural to the body. It's a very strong attachment, strong enough that you can tear the ligament without tearing it away from the bone.

THE COURT: It will stay hanging onto the bone.

MR. RONCA: It will stay hanging onto the bone.

If you have a bad enough injury that you have torn it away from the bone, that's much worse than just tearing the body of the ligament itself.

THE COURT: All right.

MR. RONCA: And you can get an idea of the motions, when the knee flexes, of those two ligaments.

All right. Let's go to the next slide.

Now the muscles.

We talked about the quadriceps muscle before. It is the main muscle that straightens the knee out, working through the patellar tendon and the patella as a leverage device.

In the back we have the hamstring muscle in the back of your thigh. There is a popliteus muscle I will mention in a minute. And then the gastrocnemius muscle is your calf muscle in the lower leg. They combine to do the flexion of the knee, although most of it is done by the hamstring.

If we stop for a second.

The popliteus muscle, that little one that came across in the back.

THE COURT: Yes. That's one I have never heard of.

MR. RONCA: The knee doesn't just move in flexion and extension. It also has some rotational forces on it. So if you can, picture yourself walking down the steps, your Honor. When you are off one foot and you are basically balanced on one foot as you are going down the steps, your center of gravity is central to where your knee is. It's not directly over your knee. So your knee is going to get a rotating force that it has to resist or you are going to fall down.

And that's what that muscle wrapped around the back partly does, along with the other bigger muscles, is, prevent the knee from -- if I can demonstrate again -- rotating on itself. Although in the motions, it does rotate a bit on itself, like this (indicating). It's actually designed to work that way.

So the forces mostly on the knee are this bending and straightening.

THE COURT: Right.

MR. RONCA: But there are also some rotational forces.

Now, if you are involved in sports, you will get a lot more rotational forces. You can picture a basketball

player planting their foot for a lay-up or a football player cutting, a hurdler. You can see how the forces would be much, much greater.

But in typical normal life, you do get some rotational force on the knee, which the knee has to account for.

THE COURT: And not to jump too far ahead, but do the artificial knees also have a little bit of that -- they must have the same kind of movement, otherwise you wouldn't be able to walk down the steps without --

MR. RONCA: Right. They do account for that artificial movement because the supporting soft tissue structure, the two outside ligaments, and then, in some cases, the posterior cruciate ligament, or the two outside ligaments and this post, prevent it from moving too much so it moves out of the joint.

So yes, it does accommodate that.

THE COURT: A little bit.

MR. RONCA: A little bit.

Okay. You can continue with that.

So we talked about the movement of the knee and how -- you have heard flexion and extension. So that's flexion where the hamstring muscles are pulling the knee down. An extension is when the quadriceps muscle straighten the knee out. These are two of the most powerful muscles in

the body, along with the gluteus muscles.

In motions of everyday life, you can have loads up to five times your body weight on your knee. And it's concentrated in the knee. And in sports activities, it can even be higher.

Maybe what we will do right now is -- let's segue to the slides again and go to the different types of joints.

Next slide.

Okay. So which joints are affected by the weight of the body and develop arthritis?

The development of arthritis is directly proportional to the stability of the joint. So the most stable joint in the leg is the ankle joint, which is a mortise joint, or a joint where bones fit together and spread the weight.

The second most stable type of joint is like the hip joint, a ball-and-socket joint, where you have bony structures that support the weight.

The knee is that third type of joint, which is held together with, literally, what we call soft tissue, soft tissue only because they are not bone. They are very strong tissues, but they are flexible, ropelike tissues holding it together.

So the knee being the most stable is -- the least stable is the most susceptible to arthritis, followed by the

hip, followed by the ankle. In fact, ankle arthritis is rare compared to the other two, and that's why we have lots of hip replacements, lots of knee replacements, but few ankle replacements.

Now, also important to the knee is the geometry of the condyles.

If you could, freeze it there for a second.

The condyles themselves are egg-shaped, so they have two radii. They have a long radii and a short radii. So when your leg is straight, you have the long radii and the long circumference supporting weight for more area.

Now, when the leg is flexed, you will see -- if you will, let it go.

When the leg is flexed -- we are coming up -- what you will see is that it rotates back and it gets off of this long circumference and gets on to the shorter circumference back here (indicating). So the weight and pressure is supported by less area.

THE COURT: Got it.

MR. RONCA: It's going to reflect back in a second. This one was longer than I had hoped, and I can't make it go faster.

What I should do now is --

THE COURT: Here it goes.

MR. RONCA: We even have our little scale there for

you, so you can see the degrees. And I should possibly insert a humorous anecdote, but I have none, so we will have to . . .

And you can see at the extremes it's really even off of this radii and on the back. If you are thin enough, you can actually literally hit bone-on-bone here with your tibial plateau.

Next slide.

Now, what happens when the cartilage starts degenerating?

Well, over time, with age, there could be injury. There could be wear and tear. There could be the cartilage is -- no longer has the fibrous tissue. The cells don't work as well. They don't absorb the nutrients as well. Maybe have you have lived an unhealthy lifestyle and you don't absorb nutrients or have as many nutrients.

And what happens is, the cartilage starts to break down. This beautiful, smooth matrix starts to break down and it causes grinding.

Now, when it starts to run roughly over each other, there is a different type of pain that can be caused than what I mentioned before about the pressure points in the bone, and that is, inflammation can be caused in the joint capsule where the synovial tissue is, which is full of all these blood vessels, inside the knee joint. And as we know,

inflammation causes pain. That's why anti-inflammatories stop pain. And that's all generated by this.

Again, the pain is not in the cartilage itself but in the surrounding tissue.

Next slide.

Literally, if you get really, really advanced degeneration of the cartilage, you can have bone-on-bone rubbing. Or if you get an injury like what they call a chondral or cartilage defect -- so you take a big smack in a car accident, your foot is on the brake and your car gets hit, your two bones come together and just knock a chunk out of your cartilage. And it does not grow back.

You can ultimately develop wear where you have bone on bone. Remembering again that bone has nerve endings. When bone rubs on bone, you are going to get pain because there isn't that lubrication in between.

So when you have these types of circumstances, it can be dealt with through rehabilitation. It can be dealt with through pain relievers, anti-inflammatories, injections. There are many nonsurgical ways to deal with it.

But one other way to deal with it is to replace these damaged surfaces of the joint so the joint will operate without pain.

One other thing to point out here -- if you will, freeze that.

The other thing that develops -- go back. Go to the end. I just want to do the bones. Thank you.

Bones over time will develop what are called osteophytes. Osteo always means bone. Phyte means growth. So there's a growth on the bone, little bumps. And these contribute to the problems of the movement if they interfere on the moving surfaces.

Okay. Now, so we get to the point where someone needs a knee replacement surgery.

Just going back slightly historically on knee replacement surgery. The big breakthrough on knee replacement surgery was, they realized that they didn't have to replace the hinge, but they could replace just the surfaces upon which the thing slides.

The second big breakthrough was when they were able to develop instruments that you would use in the surgery so that a whole bunch of different doctors could replicate, basically, the same surgery by using the instruments for cutting and for lining things up.

When they were able to do this, they were able to sort of standardize it and make these surgeries very, very successful.

One of the successful inventors, as we indicated in the papers, was Insall. And Dr. Insall's invention was one of the primary bases for the NexGen line of knees.

We want to say that the standard NexGen knee is a very successful, low-revision piece of equipment. And it's been used for many years very successfully.

Now, at this point we want to get into what the replacement -- what this case is about, is knee replacement surgery. We want to get into that.

And, your Honor, when did that, we did that in two ways. We have an animation of the surgery, broken down into different parts of the surgery. But we also have video clips from the Zimmer Web site of actual surgery. We don't think that the animation displays to you or anyone else exactly what's going on as it is in real life. So we wanted to show it.

However, it is surgery, so it's graphic. It's not a lot of blood, if blood bothers you. There is hardly any, in fact. But it is a bit graphic because they are going to cut through tissue, et cetera.

You good with that?

THE COURT: I am fine with that.

MR. RONCA: All right. So let's start with the slide on the incisions. Thank you.

So there are two types of incisions that Zimmer has promoted for their knee replacement procedure.

One is a standard or traditional incision, which is roughly eight to ten inches in length. That varies per

patient, size of patient. It varies per the anatomic marking places.

They also promote what is called an MIS. Some have called this minimally invasive surgery. It's actually Minimally Invasive Solutions, a trademark acronym. That's a shorter incision and with modified -- some modified instruments and some modified pieces so that they can fit into the smaller incision.

So the first video I am going to show is actually the incision, because you can see -- when they open it up, you can see the patella and you can see the different structures that they are cutting through.

So if we can, go to that, please. Make that bigger. We have sound?

(Said videotape was played in open court.)

THE COURT: This is a Zimmer video?

MR. RONCA: Yes. It's available on the Internet.

So you can see here, he is cutting around the patella and along the patellar tendon, along the fibers of the tendon, not cutting across it, so he can move the patella out of the way and see inside.

THE COURT: Yes.

(Said videotape continued to be played in open court.)

MR. RONCA: Synovium we mentioned.

(Said videotape continued to be played in open court.)

MR. RONCA: So the first part of the meniscus is coming off, that shock absorber.

THE COURT: Right.

MR. RONCA: Now, we go to the next part. First an animation.

So here is someone with advanced osteoarthritis. The first thing that's going to happen is, you will see that the thing will be reflected open. The patella moved out. They will bend the knee so you can see the bottom.

Now, this shows it in red. Arthritis doesn't appear red. It's just to emphasize it. It appears white.

They attach a device, a guide. And they use a saw to saw off the top of the tibial plateau.

THE COURT: Got it.

MR. RONCA: And when they saw off the top of the tibial plateau, they expose that latticework bone that I mentioned, which is important for connection.

THE COURT: Right.

MR. RONCA: And they drill a hole so they can place the femoral guide. And you will see these tools look like something from your tool shop.

And then they use a device to saw off the end of the femur the same way, sawing off the diseased tissue and

leaving the cancellous, or lattice-type work, bone exposed.

THE COURT: Okay.

MR. RONCA: Now if we can, switch to the video.

THE COURT: And this again is a Zimmer --

MR. RONCA: Yes.

Stop it for a second.

This is a Zimmer video. This is all taken from a Zimmer video. It's available on the Internet.

THE COURT: And doctors would consult this when they --

MR. RONCA: Right. It's a technical video on surgical techniques. We have edited it some so there was enough time to show it. It probably runs about 12 or 15 minutes total. We have edited it down to six minutes. We left off the beginning and the end, and we just covered the middle part.

THE COURT: That's fine. All right. So now --

MR. RONCA: Also, one thing. It's an LPS-Flex surgery. So it's one where they are going to take out the posterior cruciate ligament and leave that post, as opposed to the CR surgery where they leave that posterior cruciate ligament in.

THE COURT: This is a more invasive --

MR. RONCA: Right. That's why we wanted to show this. We couldn't show two or three, so we showed this one.

THE COURT: So now we are using the instruments.

MR. RONCA: Yes. Correct.

Notice the oscillating saw. And the reason I say that -- proceed.

(Said videotape continued to be played in open court.)

MR. RONCA: Freeze it for a second.

You can see that in the full surgery, where they don't use the MIS approach, you can see the entire part of the distal end of the femur.

THE COURT: Right.

MR. RONCA: In the smaller surgery, with the smaller incision, literally the tissue is stretched across there, and the surgeon cannot visualize the lateral or medial back end.

THE COURT: I see.

MR. RONCA: Go ahead.

(Said videotape continued to be played in open court.)

MR. RONCA: That device is called a Bovie. It's an electrocautery cutting device.

(Said Videotape continued to be played in open court.)

MR. RONCA: So we can go back to the animation, please.

So in the next part of the surgery, a guide is placed on the bottom so further cuts can be made to shape the femur to receive the femoral component of the device.

Part of the reason that the device stays on the femur is the geometric shape. Part of the reason is the attachment to the bone, but part is the shape. So you have to shape it to fit. So several cuts are made.

The oscillating saw blade is about 1.2 millimeters thick. And even though it goes through those guides, it has a flutter in it like any saw, so it makes a wider cut, depending on the skill of the surgeon, than just 1.2 millimeters.

Then they use a chisel to remove those osteophytes that we mentioned, the little bony growths, just to make sure there is nothing that impinges.

And they need to clean out this intercondylar notch because what they are going to do is put a slot for that post that takes the place of the posterior ligament to go into.

THE COURT: Right.

MR. RONCA: Go to the video.

(Said videotape continued to be played in open court.)

MR. RONCA: Sizing.

(Said videotape continued to be played in open court.)

MR. RONCA: That's the piece cut off. It's a measuring device.

(Said videotape continued to be played in open court.)

MR. RONCA: There goes the ACL.

THE COURT: Okay.

(Said videotape continued to be played in open court.)

MR. RONCA: Let's go back to the next animation.

So then drill holes are made because the femoral component, the Zimmer, has two posts, two smooth posts, that go into those two holes that are drilled.

Now the, what he said, important posterior cut is made, or the cut of the back. Now, this cut has to be made with this exposure, but also, if you can, picture in the MIS exposure with a much less visual field than you would have when you are looking.

THE COURT: Yes.

MR. RONCA: So you can see now the back of the condyle is being cut off and the condyle now has this very sort of squared-off geometric shape.

Go to the video.

(Said videotape continued to be played in open court.)

MR. RONCA: So he mentioned sizes in there. So

these implant components come in different sizes, about 2 millimeters apart, so very small differences in size.

Go back to the next animation. We are near the end.

So then a hole is opened up in the tibia because the tibia is going to have something that goes down inside of it, a stem to go inside of it, or a keel to place it in.

This -- freeze it for a second.

So this becomes the articulating surface. This is a piece of polyethylene. It's a plastic, very sturdy, long-lasting. And this is what the metal, the new replaced surface of the femoral condyle, the metal is going to rotate on.

Go ahead.

Again, stop a second.

This is the post that replaces the posterior cruciate ligament. And it will fit into the notch in the top so that when the knee is in a position where it could slide, that will resist the sliding motion. In other surgery there would be an opening there, and that posterior cruciate ligament would still be there.

Replace the back of the patella also. It's another articulating surface which would be moving through this groove here (indicating).

Go ahead.

And that's your completed implant. Tibial tray, articulating surface, femoral component, patellar articulating surface.

You can see the bones are still there. The outside ligaments are still there. In some cases, the posterior cruciate ligament is still there. The ligament from the patella is still there. That popliteus muscle is still there. All those connections are still there. You are just replacing the surface.

Now stop for a second.

Another important thing to remember is that bone is composed of cells and proteins and calcium. The reason why bones are hard is because of the calcium that's absorbed into the collagen. The collagen is the connecting proteins. The calcium gives it hardness. And the cells provide the nutrition. And it's made up of living and dead cells.

The articulating cartilage is made of collagen; proteins; other proteins; and living cells, chondrocytes. These are heterogeneous, heterogeneous, however you pronounce that. They are different substances working together that are living and have flexibility.

When you replace them, you are replacing them with cobalt steel and plastic, polyethylene.

THE COURT: Right.

MR. RONCA: Those are homogeneous substances. So

you are connecting, literally, a homogeneous stiff, steel substance to bone, which is a living substance. And you are replacing that articular cartilage that we described with plastic.

Go ahead. The final implantation.

(Said videotape continued to be played in open court.)

MR. RONCA: Stop for a second.

So again, here is the fit over the top of the redesigned femoral component. Now, the cement -- that impacting pushed the cement into the latticework that was exposed.

THE COURT: Right.

MR. RONCA: That cement is not like glue but rather like mortar. So it's a substance that has -- it is an acrylic substance. The back of this femoral component is coated with the acrylic in the factory. When the acrylics come together under pressure, what they do is, they bond as one. So that's how the cement is bonded to the femoral component. And then it's pushed into the latticework and then it hardens.

So once it interdigitates with the latticework, then it hardens. And that's what provides the grip.

THE COURT: Okay. Is it actual cement?

MR. RONCA: No, no. It's an acrylic, you know,

like a clear acrylic, like glass that you see. It's an acrylic like that.

THE COURT: Okay.

MR. RONCA: And it hardens like that. It's soft when it has the solvent. But the solvent goes away, and that leaves the hard. And it dries quickly and bonds.

Go ahead.

(Said videotape continued to be played in open court.)

MR. RONCA: See it rotating right on top.

THE COURT: Yes.

MR. RONCA: Let's go back to the next animation.

So the implants work well. Here they are represented in place with just the bony structures. And as the knee is flexed, you can see once again -- stop it -- this different egg shape still pertains, the different radii and the different circumference so that if you were flexing -- can you move that back so it's flexed in the, say, 90. Good.

You can see the amount that is actually in contact with the knee -- with the lower part.

And now -- if you will, move down to 155 -- you can see the effect.

Now, I want to at this point -- if you will, freeze that there -- demonstrate a couple of things.

Go to the slides, please.

First of all, let's talk about cemented versus noncemented because you didn't see the noncemented.

THE COURT: Right.

MR. RONCA: In the cemented version, as we said, this white represents the cement which interdigitates with the latticework bone in both places.

In a noncemented, the back side of the components are made with a porous or beaded-type metal configuration so that the bone will grow into that and make a similar bond.

Why do one? Why do the other?

For a long time and until recently, cement was the gold standard, and some would argue it's still the gold standard, but others argue otherwise because it has some negative parts.

First of all, when that solvent goes away, it goes into the bloodstream and literally increases the risk of emboli. In fact, if you look at an echocardiogram while this is being done, when they put the cement in, you can actually see the emboli coming into the heart.

Now, most of the time, the vast majority of the time, they are too small to cause any problems. But once in a while, they can cause a big problem. That's one problem.

The second problem is, if you ever have to do a revision --

THE COURT: You have to scrape all that out.

MR. RONCA: That's all got to come out. You've got to start with new bone.

These don't have those two things. Okay.

But there are those who argue it doesn't have the strength or fixation.

THE COURT: Right.

MR. RONCA: Next slide.

Now, the Flex systems were first sold in Asia where there is a substantial part of their cultural identity which has to do with squatting, sitting cross-legged, or praying like a Muslim prayer with your knees bent. So they are bent all the way back, past 120 degrees, which your typical standard implant can achieve.

When they were marketed in this country -- go to the next slide -- they talked about these Flex knees not for these social necessities but for an active lifestyle. They talked about people resuming many of the physical activities they had come to enjoy. And they talked not just about sitting cross-legged and squatting, et cetera, but gardening, golfing, running. We have some other examples, and there are many examples where it's expounded on what people could do.

Now I have to do a bit of a demonstration.

If you want to bend the knee beyond 120 degrees -- most of your activities of daily living do not require bending your knee beyond 120 degrees. Getting in and out of

a car, going up and down steps, getting out of a chair, walking, these do not require that kind of bending.

Some activities do. For example, if you were to get into the position of, say, a baseball catcher, a traditional western squat on your toes (indicating), what happens is, you have the knee, it's bent all the way around. And at some point my thigh and calf are going to come together, depending on how big my particular legs are. And that will cause a fulcrum point right here, with the weight behind the fulcrum point, creating a lever.

A distinction is that most Asians do not squat that way. They squat flatfooted, which keeps the shin bones straighter and takes some of the weight and pressure off the knee.

So if we go to the next slide.

So in the course of the marketing of the devices, they show these various positions where the knee is bent the whole way, and actually a photograph showing what we just showed in the animation, the tipping back and the extended articulating surface, which is how Zimmer was able to effectuate this, was by making this piece thicker and extending the articulating surface -- okay? -- and extending the condyle.

Some other manufacturers do it by cutting off the end of the articular surface and creating an angle there.

Zimmer didn't choose to do that.

Next slide.

Again, another reference to "patients today want to continue their previous lifestyle even after total knee replacement."

Next slide.

So this is what I was talking about in terms of squatting. And it's also like a nutcracker effect. In fact, I have a nutcracker. And if I have a nut like that, I cannot crush that nut in my hand. But using the nutcracker, I can crush it with the same amount of strength because I am using the same hand. I can even use less. And the reason for that is the leverage on the end of the lever arm of the nutcracker.

Now, those same kinds of forces affect the knee where people contact.

Next slide.

So this fellow is bending down with one knee down. You can see the weight is behind the fulcrum point. The fulcrum point is right here (indicating).

What do you think is happening in the knee when that happens?

You are getting a force this way and this way, pulling it apart, just like it would pull apart the end of the nutcracker if it wasn't attached so strongly with a piece

of metal.

The other thing about squatting that I want you to picture is, if a person squats on their toes, is that when you squat on your toes -- I can't even really do it with this knee because I hurt it.

Remember we said this patellar tendon stops stretching past 30 degrees.

THE COURT: Right.

MR. RONCA: So what happens, then, when you are squatting like this?

It's pulled tight over the top. And now the muscle, of course, is also acting and tightening to try to keep me balanced in this position. So you are adding an additional force over the top of the knee, pressing downward.

Go back to the animation where we were. Let's go toward the end where it's at 155 degrees. Stop it there.

If you can, picture that patellar tendon coming over the top and attaching here (indicating) and being pulled tight with the patella now on top of the femoral condyle, where is that force being expressed?

Straight down through onto this same spot.

Continue with this animation until it's over.

So if this motion continues with that kind of weight and pressure -- it's not running. It's not running. Click it on the arrow. Now we are back at the beginning.

What's going to happen is, it's going to repeat several times, and what can happen is, you can develop damage to the articulating surface being compressed, damage to the bone beneath it, and lifting -- because remember, these are steel pieces. They are solid. A force expressed here will be also expressed here. A force expressed downward here will be expressed upward here (indicating).

And if it keeps going -- and we are having difficulty with this one, so we are just going to -- oh, is it the next one? I am sorry.

(Said videotape played in open court.)

MR. RONCA: You will see, as this gets to the end -- had I thought it would take this long -- it seemed really short when I was doing it.

It's going to start showing wear here (indicating). See it? And here (indicating). And lifting on the front end.

Okay. That's good enough.

THE COURT: In other words -- I see. All right.

MR. RONCA: So why do the plaintiffs think that there are problems with this particular knee and what science -- what reporting supports that?

Let's go to the slide next, please.

The FDA has a voluntary system of adverse event reports. Now, I think most people have a reliance on the FDA

to be very careful about what devices are put in our bodies, what drugs are put in our bodies, foods and everything else.

But the vigilance of the FDA varies with the type of device. For example, drugs have always been required to have premarket approval. Go through an elaborate application process and go through elaborate testing and prove to the FDA safety and efficacy before it can be marketed.

Originally, medical devices were not included in the act and were only added later. After they were added, there were already tens of thousands of devices on the market, and it was impossible for them to go back and check them all. So they allowed what they called a 510(k) clearance, which clears the devices for marketing without that elaborate testing that we talked about.

In fact, if the elaborate testing is done, which is only done on about 10 percent of implanted devices on the market, there is preemption against claims of design. But if you elect to have a 510(k) procedure, which then relies on predicate devices to say, hey, the prior device worked, this one will work. We have designs -- and most of the testing is done on the bench, like with design rationales, drawings, computers, or maybe the device going through a machine with measurements. They are not done in vivo, in life, in real people like drugs are typically, or it's minimal.

Once it gets out in the real market, that is where

the problems begin to appear.

Now, post-market surveillance is also not the best because it's voluntary. And the system is, the doctor needs to send it in when they think there is a problem, but there are plenty of published articles that say -- and including the FDA's own articles -- which say that tends to be underreported by a factor of 10 to 20.

So what we see is, the reported incidents of Flex reported. Now, there are plenty of these reports that don't mention whether it's Flex or not. It doesn't really identify from what we can see, because we are still subject to only public documents except for the 10,000 pages we got before yesterday.

But you can see that there is an upward slope of failures, that the failures in 2010 were 100, which could be a thousand or 2,000 because of the underreporting. And the failures in 2011, which you don't see, were only reported through June, but there were 100 through June, meaning potentially for 2011, there could be 200, meaning there could be as many as 2,000 to 4,000 failures.

Based upon the number of Flex that we think are being sold, which we don't know for sure, we think that would be a high failure rate compared to the standard.

Now, let's go one more step, please.

So in terms of having it approved -- or cleared,

not approved, cleared for marketing, these are the 510(k)s and the numbered applications for the various devices. You can see the non-Flex standard, CR, and LPS provided the basis for every one of these devices. And in most cases, except for minor design changes, they were called identical or substantially equivalent.

The non-Flexes, the standards, they were based on even earlier devices by the same process.

Next slide.

Also pointing out that the MIS tibial components had the same progeny as the Flex components.

Next slide.

So the first article that was published and referred to in the -- on our paper was the article by Han. And what Han did was, he followed a certain number of people with one surgeon, so the same technique for each, an experienced surgeon. And what they found was a high incidence of failure. I think it was 38 percent of loosening and 21 percent revision.

And these were X-ray photos from Dr. Han's article showing where it's lifting off on that femoral component, as we demonstrated earlier with the animation.

Next slide.

Then, in 2010, a physician by the name of Dr. Berger from Chicago, at the Rush Institute, and

Dr. Della Valle got up at the American Academy of Orthopaedic Surgeons' meeting and gave this abstract presentation, that they had done -- two surgeons in their department had done a certain number of knees. They had reports on 108. And of these 108 knees, 39, or 36 percent, were loose; and nine had to be revised. And these were high implant rates.

And what did these doctors say in front of the general national meeting of all the orthopedic surgeons? They said, this component is still commercially available but should not be used for any patient.

Furthermore, this report highlights the need for clinical studies -- that's studies in humans, not on the bench -- prior to new design implementation.

Next slide.

And who's Dr. Berger? Dr. Berger was a Zimmer consultant and received, for example, in 2007, $2.2 million from Zimmer. In 2008, he received $5.7 million from Zimmer.

Now, how do we know this?

This is on the Zimmer Web site. And the reason it's on the Zimmer Web site is because all of the orthopedic device manufacturers had entered into a system where payments were made to consultants in high amounts across the country, and they were all subject to deferred prosecution agreements, which required, in Zimmer's case, them to pay $169 million in civil penalties and also post on the Internet the consultants

who were paid in 2007, 2008, and 2009.

In 2008 they paid consultants roughly $85.5 million. And the whole issue was, were they getting paid for their hours? I mean, $5 million would be a heck of a lot of hours.

Next slide.

There are also other articles that we didn't mention in our paper, but I will bring to your attention just one.

This is an article in the *Journal of Bone and Joint Surgery*, a peer-reviewed journal, from October 2011 by Dr. Bohler and others. What they did was test high-flexion designs from five different manufacturers. Their conclusion was, the high-flexion designs have a greater risk for femoral component loosening than conventional or standard total knee replacement designs. And they give the technical reason: the absence of the femoral load sharing between the prosthetic component and the condylar bone.

Next slide.

So they made a bar chart of the force that it takes to loosen particular implants. On this side, these are all the Flexes, five different manufacturers. On this side, these are all the standards. You can see generally the standards require more force in order for them to loosen.

And what we can show -- next slide -- is that the

Zimmer NexGen Flex was the lowest by far -- in other words, the least amount of force needed for loosening -- amongst all the Flex implants. And actually, the Zimmer NexGen standard was the least amongst all the standard implants.

Next slide.

Now, the defendants, in their position paper, point to a letter that a Dr. Giles Scuderi wrote and got published, critical of the Han article that we mentioned before.

So who is Dr. Scuderi? Dr. Scuderi is the same person that was in that promotional piece that we showed you earlier. And Dr. Scuderi is also a Zimmer consultant who, in 2007, received approximately $900,000. That's the year he wrote the letter. And in the next year, he received $4,700,000 as a consultant for Zimmer.

Now, the plaintiffs have reason to think that possibly there might be some credibility issue there from the person who is criticizing another physician who published a peer-reviewed article and did not have similar connections.

Next slide, please.

Are we done?

Let's complete the failure animation and make a few comments. And then, unless there's questions from the Court, I am finished.

So the plaintiffs believe that promoting this device in high-flexion activities leads to early loosening.

The defendants put a lot of confidence in the Australian registry. We believe the Australian registry still shows a higher rate of failure for the Flex versions when compared to the regular versions.

Now, does the Australian registry provide some good information? Yes.

Is it the be-all and end-all of information? No.

First of all, it has no controls. It's just reporting.

Second of all, the reporting is done by database.

Third of all, they don't do as many knee replacements per capita in Australia as we do here. In fact, they do about half; meaning, in the U.S. we reached the margins of the bell curve of people who should get this more completely than they do in Australia.

Fourth, it's a relatively low number compared to the total number. The total number of knee replacements in Australia for ten years is less than half of the total replacements in the U.S. in one year. And that's for all devices.

It's a single-payer system, meaning that people go to big centers to have this done. You don't have community hospital physicians doing knee replacements out in the middle of the Outback. People go to hospital centers, to surgeons who are doing these things all the time. They have a more

homogenous population. They have a less obese population.

So there's a lot of factors that you could take into account when you look at the registry and say, this is the be-all and end-all of information that we need about these devices.

Our position is that the devices have a higher failure rate. It's related to the design and instructions of the device and that we have a case.

If there's no questions, your Honor, I am finished.

THE COURT: Thank you.

Should I leave the lights low?

MR. YEAGER: If we can take about three minutes? We have to swap out some technology.

THE COURT: Certainly.

Let me turn the lights on so you can do that.

Does your presentation -- is it similar in terms of length?

MR. YEAGER: Probably about an hour.

THE COURT: All right. In that case, I will take a couple minutes myself and be right back.

MR. RONCA: Your Honor, before you leave the bench, my colleague just pointed out to me -- I just want to say that we have -- obviously still have limited information about what they have inside of Zimmer, and we are limited by that in our presentation.

THE COURT: All right.

I will be back in about five minutes.

MR. YEAGER: Thank you.

(A brief recess was taken at 10:49 a.m. until 10:58 a.m.)

MR. YEAGER: Your Honor, while we are getting ready, if I can just hand up -- these are some samples.

(Documents tendered.)

MR. RONCA: Could I look at them also?

MR. YEAGER: Of course.

(A discussion was had off the record.)

MR. YEAGER: While we are waiting, the Court asked the question about rehabilitation between hips and knees.

THE COURT: Yes.

MR. YEAGER: From what we understand -- what I understand, actually the knee rehabs are usually longer. Although you have the same basic amount of weight, it's on smaller surfaces and a more complicated surface, is what I am told.

But generally the rehabs do take longer.

THE COURT: I also notice -- again, this is not relevant to anything, I suspect, but this feels really kind of heavy.

MR. YEAGER: Yes.

THE COURT: As compared to your -- I assume my own

knee is not that heavy.

MR. YEAGER: Yes.

THE COURT: So when you have one of these, do you notice that?

MR. YEAGER: I have never heard of anybody saying that.

Andrea, do you know?

MS. PIERSON: It's amazing that patients don't notice it, your Honor.

Joint replacement surgery is one of the really incredible surgeries that are available for patients. The weight of the component is, obviously, something we consider in the design, but it's not a factor that the patient ever feels.

THE COURT: Interesting.

MR. YEAGER: And I am told they don't set off metal detectors.

THE COURT: That was another question.

MR. YEAGER: That was another question.

THE COURT: Yes.

MR. RONCA: Although, your Honor, I had a thallium stress test. Two weeks later I was going into Canada. I set off every radiation detector in the airport from the thallium in my blood.

THE COURT: Oh, my gosh.

MR. RONCA: They took me in the back room. They put a Geiger counter on me. They checked all my luggage. They thought I was bringing in nuclear weapons. It was at least two weeks later. Maybe they are very sensitive.

(Brief pause.)

THE COURT: Is it okay if I turn the lights off, or do you need the light?

MR. YEAGER: I don't need a light.

Thank you, your Honor. And thanks for giving us some time to get our switchover done.

Mr. Ronca spent time explaining largely the biology of the knee and some of the disease processes, which I think provides for a nice transition to our part of the presentation. We don't overlap too much. We overlap a little bit. But our presentation is really -- touches on the biology of the knee but really is more about the device and how the device works.

So we have one animation here, which will be familiar to you. It shows how the knee works in normal function; normal, healthy-functioning knee. It shows the cartilage, shows the patella, the patellar tendon.

The Court had asked, when we talked about our position papers initially, why does it hurt? What is the disease process?

And almost all these knee replacement surgeries are

for arthritis, osteoarthritis, the disease process that has been described fairly well already this morning.

And the Court asked a question, why does it hurt?

It hurts because there are nerve endings. And when that cartilage wears away and you get done to the bone and it's bone-on-bone, that's what causes the pain.

What we are going to talk about, how does total knee arthroscopy, or TKA, address the pain?

This is just a schematic almost, a diagram of some of the cartilage at a macro level rather than a micro level that we saw before. And you can see healthy knee, healthy cartilage. And here is some deteriorating cartilage, a medical illustration.

As that advances, you get more and more pain and restrictions.

What are the implant components? What do we do to treat this?

I know the Court will recall from some of our prior discussions something about this, but just to review very briefly. We have given the Court the four components: the femoral that goes on the femur; the tibial that goes on the top of the tibia; the articular surface, sometimes you will hear it referred to as TAS, which is the plastic -- high-density plastic piece in between; and then the patellar component.

This is just an animation that shows the different angles of the knee. So there is the knee head-on. This is a knee with the implants. And you can see the patella on the front. Quarter front view. There is the side view with the patella, the femoral component, tibial component, and articular surface.

There is the view from the back with the condyles wrapping up around from the right side.

And then back to the front.

THE COURT: Okay.

MR. YEAGER: We talked a little bit about the implant surgery. Here is our animation to kind of show the surgery front to back.

This fellow has obviously got worse problems than his knee problems.

(Laughter.)

MR. YEAGER: I am not going to stop this. We will just go on through it because it's a little bit redundant.

But I think what's important here is that these slices show the cuts.

And for some reason, it is stopped.

THE COURT: Was this video created for me, or is this used in some other context?

MR. YEAGER: This was something we already had.

THE COURT: Great. Good.

MR. YEAGER: Hopefully it will go further this time. It ran great for the last three days.

THE COURT: Never fails, right?

MR. YEAGER: So we saw some of the surgical views. This depicts what all the cuts have to look like where you had a bare bone, so to speak.

THE COURT: And when the surgeon does this, he or she already has the size.

MR. YEAGER: Well, they size it. They have a rough idea, but they size it. I think you saw some slides before.

THE COURT: During the surgery.

MR. YEAGER: During the surgery. And there are even now half sizes to try to get it to fit very, very well.

And then there's the component.

THE COURT: Here is my metal piece.

MR. YEAGER: It rotates over. Clamps on there, cemented or uncemented. Yours is a porous, so yours would not be cemented.

There is a baseplate. It would be screwed on, and then there is a tool that snaps that plastic piece into the baseplate.

THE COURT: Right.

What do you call this little round thing?

MR. YEAGER: Patellar button, I think.

THE COURT: It goes behind the patella.

MR. YEAGER: Right, because it slides. The patella has to slide over the implant.

This fellow has amazing recuperative powers because he can stand up right after the surgery and walk away.

One of the things that may become an issue in the case and I think probably already has become an issue in the case are variations in the surgical techniques that doctors may choose to use when they are implanting these devices.

We have talked a little bit about commented versus cementless. I think the Court is familiar with that.

Then, you can have conventional surgery versus minimally invasive surgery.

I want to clarify a little bit about what that really is.

The term "MIS" originated with "minimally invasive surgery." This is a surgery procedure or group of procedures that doctors initiated to try to have surgeries be less invasive. And they did it -- before they did it on knees, they did it on other kinds of surgeries that they found they could do more easily with smaller incisions. And it came to be known as minimally invasive surgery.

Device companies like Zimmer, of course, have to serve the advances of science and of medicine and the medical community and make products that will work with these procedures.

Zimmer did happen to trademark, I think, the name Minimally Invasive Solutions. So when you see Zimmer MIS, that's their trademark for devices that they have made to help these surgeons who choose to do minimally invasive surgery do those kinds of surgeries.

We talked about cemented versus cementless. Here is a slide that just illustrates the angles and the precision needed for the cuts on the bones. And the reason this is important is, in cemented -- you saw some of the cemented surgery where they put the cement in there and pounded it down and cement was squirting out.

THE COURT: He shaved some of it off.

MR. YEAGER: Tried to clean it off. Of course, it's important that you get all that off. And there are ways to do that wrong and ways to do it right.

On the cementless, because you are not going to have any grout or cement in there, you've got to have your cuts right. They have to line up with the angles on the device, because it takes bone a while to grow. And that bony surface has to be up tight and flat against the surfaces, the porous surface, on the inside of the implants, and stable for a long period of time so that that bone growth can take place.

If it's not, if these cuts are not done right, then what you get is what they call micromotion. You get a little

bit of tiny movement back and forth. And if you have micromotion during rehabilitation, before that bone has grown in -- and it takes several weeks -- what happens is, instead of bone growing in, you get soft tissue growing in. And then you don't have a very good bond, at least at that part of the implant.

You have heard discussion and we will have some more discussion about radiolucencies, and those are just little spaces on the X-rays where it shows a space, a soft space, between the bone and the implant. And that shows that maybe the two haven't met up, maybe there is soft tissue in there, maybe there is a gap in there. Sometimes that can indicate a loose component. It does not always indicate that. But that's something that doctors look for. And that's where you have had micromotion or, for some other reason, the bone has not grown in over the period of time that it needs to, to be stable.

Rehabilitation is another thing that's obviously important in the process. The surgeon controls the rehabilitation process. Obviously, the surgeon has technical information from the company that these -- every surgeon has his own process. And sometimes they share them and sometimes they don't.

Dr. Berger, our understanding is, shares part of his and doesn't share other parts of his. And that's not

uncommon, because I think surgeons believe that their process is the best. But that is something that is up to the surgeon who supposedly takes into account -- I am sure does take into account the individual patient and all the different variety of issues that an individual patient might have, as well as things like, did I put in a cemented or a cementless component?

It's simply the point I just made about the micromotion.

Why would one need revision surgery for a knee? What are the causes of problems that would create a revision surgery?

It is certainly not -- and it's easy for a lay person to jump to the conclusion -- like me, to jump to the conclusion, well, if there is a revision surgery, there must be some problem with the component.

But that is certainly not the case. There are many reasons. One leading reason is infection. If you get infection at the wound site or infection at the bone site, you can have a loosening that leads to a need for revision.

Then, there are a number of aspects of the surgical technique that have to be right. If they are not right, you are going to have a problem.

Precision of the bone cuts, we talked about that. If the cuts aren't right, you are not going to get the right

ingrowth.

Angle of implantation, which is -- you can have the bone cuts fit the component right, but if you don't have that component at the right angle to the bone, if it's tilted a little bit one way or the other, then you could end up with some forces misaligned, and you could end up with a revision.

Cement technique. There is a right way and a wrong way to do the cementing. As was explained earlier, this cement is more like a grout. It's not so much an adhesive as it is something that infiltrates the porosity of the bone, and then some of the precoating on the component, and then solidifies.

You have got to get that right. You have got to have clean surfaces, and you have got to have that worked in correctly or else you are going to have the cement not taking hold.

And part of that is cleaning the surfaces, both of the implant, making sure you don't get stuff on the implant. In that surgical field, you can see there are fluids around in that field. You have got to keep the inside of the implant clean and dry, away from those fluids, or you are going to have problems with the bonding.

Rehabilitation, another reason for revision surgeries. There's an amount of weight bearing that's good, that promotes healing, and then there is an amount that is

excessive, that will cause micromotion or cause the thing to come loose. And that's why the doctor has to give the patient the right instructions, according to the doctor's protocol. And then the patient has to follow those instructions. And if those things don't happen, you can have problems with the fixing of the bone to the component.

Biomechanics are kind of a broad term the company uses and has used in the orthopedic community just as a broad term to describe the function of the knee. How is it lined up? Is it straight? How were the tendons balanced? Is it sized right? Does everything work together right? If it doesn't work together right, you can have some misalignments that can cause a need for revision.

At some point in the life of a component, ultimately you can have wear of these plastic -- the plastic component, the plastic articular component that takes the place of the cartilage. And then that can impact other components. They can become misaligned.

Again, in some components -- we don't have this issue in this case, I don't believe -- you can have reactions -- body reactions to the bone cement. Actually, we do have that in one of the cases. Metal debris that could come out and -- or just a reaction, almost like an allergic reaction, to the plastic. That can happen.

And then there is the whole issue of bone quality,

whether -- some of these folks are not in good health, and they may have deterioration because of health or age, where their bone stock isn't good enough to support this.

The weight of the patient is obviously a factor. Greater weight puts more stress on during rehabilitation and afterwards.

The level of activity of the patient is also a big factor. The more active you are -- there was a diagram earlier of a gentleman who was kneeling down on one knee. The more active you are, the more stress you are going to put on your component. There is no doubt about it.

And then -- I have given a long list. And then, device issues. If there is a defect in a device, that could be another reason that can cause a revision surgery.

But before one figures out why revision surgeries happen -- why certain statistics for revision surgery occur or why a particular surgery has occurred, you got to look at all of these. And you can't just jump to the conclusion that it was a problem with the device. In fact, it usually is not.

The Court asked at our last hearing or maybe two hearings ago for a little bit about the history.

THE COURT: Right.

MR. YEAGER: This is a very abbreviated history.

There were some implantations earlier in the 20th

century, what people would talk about as the modern trend of joint replacement.

Knee replacement surgery originated in the '50s. There was a seminal paper written by Leslie Shiers in the *Journal of Bone and Joint Surgery*. There were hinges that had limited function. And then the design evolved.

And this is a very important part of understanding how this process works in the orthopedic device, science works. It is evolutionary. Every device builds on the prior device.

So the first device probably wasn't very good. The next device improved on that. The next device improved on that.

This development accelerated in the '60s and the '70s. And the number of people who were having implants really increased in the '60s and into the '70s.

So by the late '70s, Zimmer had two systems. One was the IB system. And the I is for Insall, whose name was mentioned in the earlier presentation, one of the pioneers of this.

And this is what later became or very similar to an LPS system.

Then, the other one we had around the same time was the Miller-Galante, which is cruciate retaining. There is some more detail on the slide that I don't think we need to

linger over.

The point is, we had these two systems. They came from these sets of doctors who had different philosophies and were creating a product. And you can see the product looks somewhat similar to what we have now.

THE COURT: Right.

MR. YEAGER: The next level of development, then, was the combination of these and refinement of these into the NexGen system in 1994. So it combined those two lines so you would have in the same group, with the same kinds of instruments, an option for either retaining or sacrificing the posterior cruciate ligament.

So the doctors could go into the operating suite and have both of these options there. And when they get into the knee, it would be easier for them to switch from one to the other. That's kind of the high-level view of it.

But probably more important than that is just the advances in geometry. Again, having 15 years with these systems or more, having a large number of surgeries -- at this point there had been tens of thousands of surgeries, and they were really beginning to get some data about what worked and didn't work.

So they made numerous little revisions to get to NexGen.

And NexGen was very clinically successful. It

worked well. Doctors liked it. And doctors did implant a lot of them, as I think was acknowledged this morning. It's been a very successful system.

I put the same animation there so we can see the NexGen system having rotated around one more time.

So what happened next?

After the NexGen system was introduced and as it was being implanted in more and more folks, doctors began to observe that the geometric changes had really allowed people to flex more than had been anticipated and to flex more in general than they had with the older systems just because it was a better system. The structure was better and the geometry was better.

And physicians in -- it did start in Asia -- started talking to Zimmer. And I am sure these same things happened at other companies, which also introduced Flex models of their knees. These physicians started talking to people at Zimmer and saying, you know, my patients who are on their knees a lot for cultural reasons, squatting, cross-legged, they are getting a lot more flex. They are not at 90 degrees or 110 or 120. We are seeing them up to 140, 150 regularly. And that's great.

But these doctors would ask and Zimmer started to discuss with them, what can we do to make sure that -- now that we have this increased flexion, what can we do to make

sure that it is not going to have some adverse effect? because these folks who have that flexion a lot, unlike people in other cultures might, although very active people perhaps would, they would be up on these high flexions more often.

So Zimmer started looking at, what do we need to do to make sure -- since we are getting this really very excellent flexion, what do we need to do to make sure that that's going to be safe and that our components are going to last and they are going to accommodate this flexion correctly?

As I mentioned, other companies were having the same kinds of experiences.

THE COURT: Right.

MR. YEAGER: This is an important point. And whether it will be an issue at trial, I don't know, but the Flex was not designed to create this higher flexion. And there has been some back-and-forth about that in the papers of the parties.

As I described, it was designed -- the Flex changes were made to accommodate the flexion that was already occurring.

As to whether it does or does not actually create more flexion, there are some signs on both sides of that. I am not sure that's a fight we need to get into, but I will

return to that in a bit.

That's not the intent of the device. The intent is so that when you get into higher flexion and if you are a person for cultural or athletic or whatever reasons get into higher flexion more often, your knee is going to work, and it's going to work in the long-term.

Okay. So I am going to talk now about the changes that were made, because this case, according to the papers and the argument and the JPML is about the engineering changes that led to the Flex design and whether those have created a defect. That's how we ended up in this court.

So I want to talk about what those engineering changes are precisely.

This is a non-Flex device, an X-ray of a non-Flex device at 155 degrees. You can see that the -- it's not entirely up on the point of that femoral condyle there, but it's getting there. So rather than being flat, as you get up there on a non-Flex device, you are getting all that weight concentrated on one spot. And Mr. Ronca talked about that and, I think, made a good point. It's better to spread the weight out. It's better to spread out the footprint.

And here is a person kneeling, also at 155 degrees, but this one is an LPS-Flex. And you can see here, rather than it being up on the point, even though we are at 155 degrees --

THE COURT: There is more surface.

MR. YEAGER: Exactly. Bigger footprint, less wear on that poly.

This is a CR-Flex. And the picture is not as good. It makes the same point. It's not up on the point.

Now, here is a diagram that shows the changes to get this contact area. And it's as you would expect. Here is the Flex. The curve is different. And you have greater contact area here. You are up on this point.

THE COURT: That's the non-Flex.

MR. YEAGER: That is the non-Flex LPS design versus LPS-Flex design.

Judge, I don't mean to hurry through this. If you want me to slow down, I will.

THE COURT: You are doing fine. This is good.

MR. YEAGER: This is, I think, one of the most important slides that we are going to have today. And I want to talk about it for a minute because it shows the impact of the Flex changes on the footprint.

This is a chart of Flex -- CR versus CR-Flex. The CR is the diamonds in the blue. So that's the preexisting design. And then the CR-Flex is the black with the boxes.

And what this shows you is footprints versus flex. How big is the footprint of each product at various levels of flexion?

So you can see that this is low flexion, where you live most of the time. This is where you walk. You get out of a chair, you might be over here. But this is where people live most of the time.

And then over here are the levels of higher flexion. And here is the real high flexion where you get those very high forces that we have been discussing.

So how did the changes in the shape of the components on CR-Flex affect the footprint? You can see they affected the footprint very favorably at two important places.

Here, the footprint -- this contact area is the measure of footprint, how big. And bigger is better.

Look at this. At 10 degrees, which is essentially where you are a lot of the time when you are walking, the CR-Flex --

THE COURT: Had much more surface.

MR. YEAGER: More surface area. Spreads that load around.

They gave up a little bit, a tiny bit here, maybe 5 percent or so along through this line.

And then the key, the design -- or the point of the design that we were trying to achieve is right here at the end, when you get up on that point that we saw, when you are at high flexion. And there, the old design was way down,

down here. But the CR-Flex, because of the shape of those condyles and the extension, stays with a fairly large contact area, a large footprint.

So both at the low, where you live all the time, and at the high, where you have these high forces of flexion, you are better off because the CR-Flex provides a benefit, a spreading out that is going to manifest over the long run.

Now, these things don't wear out typically right away. The question is, are they going to wear out in 7 years or 10 years or 15 years or 20 years? That's what this has an impact on.

Okay. Second engineering change -- and there are many. I am going to cover three, but there are several. As we get into the experts, I am sure we will talk about others.

The second is impingement. And that is this tendon that runs around through the patella, to your quadriceps, that wraps around the front of your knee, when you go to high flex, that tendon is wrapped around the front. And if you have a square piece sticking out, it's going to rub against that piece. It's no more complicated than that.

So right there, there is possible impingement on a typical device. This is an LPS non-Flex.

So what they did is, they cut out a little. They changed the shape of that plastic component.

THE COURT: So it created a little slope there.

MR. YEAGER: Yes. The Court has the plastic right there, and you will see that there is a chunk cut out of it -- in Indiana we would call it a chunk cut out of it -- to accommodate that. And here is a picture that demonstrates the same thing. That's the second change. Again, that's a long-term thing, to make it long-term more favorable.

The third thing I want to talk about by way of these engineering changes is this shape of the tibial articular surface to keep the knee from moving back, from hopping back over the edge. If you get into very high flexion, you want to make sure you don't have the knee popping back off the tibia.

So what was done here on the LPS, you can see, both with the femoral component and the shape of the tibia, you are right there at 150 -- I think this is -- yeah, this is 155. Not much keeping you from popping off back here.

And what they did was, they just changed the -- they changed the shape. And also you have a change of shape in the femoral component and the tibial component. And so you have less risk of it popping off in high flexion.

THE COURT: Okay.

MR. YEAGER: None of these are designed to create high flexion. They are designed to accommodate it.

Obviously we can't read this. This is the profiler of all the components in the NexGen system. On the left it

has -- these are the tibial components. I'm sorry. These are the femoral components, the patellas. These are the tibial components.

And I put this up here to demonstrate, out of the whole NexGen system, what's at issue in this case.

So this is the -- that is the Gender Solutions Flex femoral component. And this is the tibial component, the 5950, which was part of the -- some of the cases that the JPML sent here were 5950 cases, these tibial cases. That's one tibial component. It works with all these different femoral components and also works with non-Flex components.

That is the CR-Flex femoral component. That's the Gender LPS-Flex and the standard LPS-Flex. And then you have cemented and uncemented versions of those.

As you look at this, you can see out of all the NexGen components, these are the only ones that are in the JPML order that was sent here. And the JPML, as the Court probably knows, has recently rejected attempts to enlarge this MDL by adding additional components, a Natural-Knee in that case.

Just a quick animation that shows the flex. And there you get to high flex. You have got a lift left so you don't have subluxation. And you get a nice footprint.

So in the science of orthopedic devices, how do you figure out whether your device is working?

You can put it in a few people and you can see that it works on those people. But more broadly, how do you figure out what it's doing, whether it's really working? What are the sources of your data?

Well, there is registry data. And you heard some mention about it before. A number of countries have registries, national registries. The U.S. is just getting started with our registry. We don't have one up and running yet.

Just a note on the units. You will see three- and five- and seven-year revision rates, which is simply cumulative rates. After three years, how many of these knees have been revised? After five years, how many have been revised? After seven?

And then there is another measure called "revisions per 100 knee years," which is a different measure we are not going to use today, but the Court may see that later on.

Another thing you look at for performance data to understand how your knee is doing is the experience of physicians who studied these things more deeply than just in broad statistics. And there are peer-reviewed papers.

One of the things you want to look for in scientific data is, is it peer-reviewed? Is there random patient selection? In other words, do you randomize it or do you just take who happens to walk through the door? Is there

a control group? Do you compare whatever you are studying against a control group where you try to control for all the other variables?

Not every study gets all of these, but the more of this you have, the better off you are in terms of reliability of the study.

There was a mention of the MAUDE FDA database. Now, that's a database that Mr. Ronca mentioned. It's not a registry because it's not all-inclusive. It doesn't, for example, track all the implantation. So you can't make the comparison that you would make in registry date -- revisions versus total implantations.

I think it's purely speculative to say what the reporting rate is. I don't think anyone really knows for certain what that is and whether it's 10 or 100 times what's reported. I don't know if there is any evidence of that whatsoever.

I would note -- and I don't have the slide because it's Mr. Ronca's slide -- that the reports that he had on his slide -- you may remember there was a bar chart running up to 2010 with more reports of failures on Flex devices as you went on.

But even in 2010, that slide, which he didn't know if it was Flex or a NexGen -- all NexGen, there were only 100 reports in 2010.

Now, what was happening in 2010 was, obviously, there were more and more devices out there because sales have increased and implantations have increased. And also, there was pretty heavy plaintiffs' advertising on NexGen knees, starting in 2010, late 2009 and 2010.

Does that have an effect on the number of reports? I don't know.

But even with the 100 reports that were reflected in that bar chart, Dr. Berger's own report, an isolated report, could account for like 30 of those.

So we are dealing with very small failure rates here. So a little fluctuation -- there is a little noise in the data from external factors.

Back to the Australian registry. The 2011 report recently out -- it's on the Internet -- analyzes about 270,000 replacements reported to the registry up through the end of the prior year. This is just a quote from the registry report. It talks about how they collect the data.

The hospitals provide the data on forms. They are completed in theatre -- in the operating rooms -- at the time of the surgery, submitted to the registries every month.

And one of the aims, the stated aims of the registry, is to evaluate the effectiveness of these prostheses currently on the market by analyzing their survival rates.

Okay. Beginning the registry data, just for an overview, here is what the data shows across all knee types for revision rates.

Five year, 3.7 percent; seven year, 4.4 percent; nine year, 5.1 percent.

So when you think about that in terms of survival rates, that means for all knee types, knee revisions, after five years, 96.3 percent are still going. 3 percent have been revised, 3.7. At seven years, 95.6 percent are still good. And nine years after implantation, about 95 percent are still good.

So we are looking at these variations and revision rates that are at the small end of the spectrum. Even at nine years, you are still at 95 percent.

Okay. I mentioned the chart before that talked about the footprint was the first one I thought was very important here. This is the second one that I think is terrifically important. And that is the five-year revision rates. I am going to only show two of these. There is lots of data in the survey. There are lots of things to look at. When we get down to experts, I am sure there will be a more thorough summary of these.

You look at how the NexGen has done compared to other implants. So here are the averages on the right for all. These are cemented knees. 3.6, five-year revision

rate.

We have picked out -- in this data there are really about, I think, either 27 or 29 knees evaluated that are in the registry, that have enough implantations in Australia. So we picked out the high and the low and the most popular. So you see the different brands and combined for this average of 3.6.

The LPS-Flex is right at 3.7. It's very close to the average of every other device in the entire registry. It's a 3.7 percent revision rate after five years.

The CR-Flex is 2.1, which is well below the 3.6 for everyone else. And there are a number of devices that are above that.

On cementless, they didn't have five-year results for the cementless LPS-Flex. In cementless, the average for everyone was 4, 4 percent revision after five years. And the CR-Flex, 2.3, a little bit more than half the rest.

And, of course, Zimmer believes that this kind of data shows that the product is not defective. This is data across an entire continent. It's across all kinds of doctors, not just one or two doctors. And it's fairly thoroughly monitored.

So that's the database, the registry data that shows the general performance of the Flex products.

There is one I just forgot to mention.

The NexGen CR, back on the cemented knees, is the lowest of all those. It was about 1.7.

So the two Zimmer NexGen products had the lowest two spots out of 29 -- out of those 29 on that part of the study.

Okay. So that's registry data.

Peer-reviewed papers. I talked a bit ago about what were the important things about peer-reviewed papers and control groups and randomizing and prospective selection of participants.

I am going to talk -- and hopefully not in too great a length -- about what a broader look at the scientific literature shows.

The scientific literature overwhelmingly shows that these devices are terrifically successful.

As always, in every field of science there are some outliers. And then one has to figure out, why are there outliers? Why do these folks have a different opinion or a different result than everybody else? And that's something that the experts will have to sort through.

For now, let's talk about -- and I will start with the outliers. The two that Mr. Ronca mentioned this morning are the outliers. Dr. Berger did have a critique of one of our products, the CR-Flex porous femoral. His critique was not a peer-reviewed paper. It was a report -- as was said

before, he stood up in front of a society and made his report about, this is what happened, this is what I experienced.

Two surgeons in the same practice, there was Dr. Berger and Dr. Della Valle, not peer-reviewed, not randomized. They just looked at what their patient experience was. There was no control group where they would compare the CR-Flex, the porous femoral component, against something else.

His result is much different from the registry data that we have talked about, confined to the one component -- in fact, he still uses other Flex components. He just doesn't use the CR-Flex porous femoral component.

As far as I know, that article has never been written. Never been submitted. As stated, it's never been submitted for peer review. And not all the data that underlies what Dr. Berger wrote has come to light. And we will look forward to finding out what happens, what our experts tell us about why he had these results that were anomalous compared to the broader data of 270,000 implants.

Dr. Han was another one that was mentioned. Dr. Han was, I believe, in Singapore, one individual surgeon. It was not random. He had no control group. Like Dr. Berger, his experience contradicted registry data.

His was confined to LPS-Flex cemented femoral component. The Court may recall, in the cementing process,

there are ways to get that right and there are ways to get it wrong.

So it is also surgeon technique sensitive.

Dr. Han concluded that he thinks the device needs more study because he acknowledged it was one surgeon. There were other limitations to his report.

So against these outliers -- and I understand there was another paper cited this morning that was not in the papers last week, and obviously that will be addressed.

I didn't take every positive mention in every scientific paper. We don't have the time for that. The Court doesn't have the time for that. But I have a few slides to just give the Court bullet points from the broader survey of the scientific data on the performance of Flex devices.

If I am going too quickly or too slowly, the Court, I am sure, will tell me.

Dr. Huang, 2005. 25 LPS-Flex. No loosening in two years.

Dr. Kim, 2005. 50 patients, LPS and LPS-Flex. One in one knee, one in the other knee. No cases of loosening or revision at two years.

Dr. Chiu, 2006. Prospective randomized study. No complications of loosening in 420 LPS-Flex knees at 40 months. That's a little more than three years, of course.

Drs. Weeden and Schmidt. Prospective and randomized study. LPS-Flex in 25 knees. LPS in 25 knees. No revisions and no radiographic differences -- radiographic evidence of loosening between the groups at one year.

Bin and Nam, 2007. Prospective study comparing LPS and LPS-Flex. No indications of loosening in 90 high-flex patients at one year.

Minoda. 89 standard and 87 CR-Flex. No revisions for loosening. No differences in radiographic parameters.

Seon. 50 CR, 50 CR-Flex. No evidence of loosening.

Kim. 54 patients. No revision. No loosening.

Tanavalee. 77 months. No revisions for loosening. 178 knees.

Matsuda, 2010. Comparing two groups of LPS-Flex, fixed and a mobile, another kind of knee. No knees revised for loosening at five years follow-up.

And another Kim study. 250 patients, no loosening and no revision at two years.

A couple of the next studies go a little bit beyond talking about the loosening or, frankly, the absence of loosening and revision to talk about a subject that may or may not become an issue here.

Dr. Seng, in a study from 2011, last year, found no loosening in 36 LPS-Flex knees after five years.

He also said -- this study was interesting because it was designed to study not only the flexion, not only the revision rate, but it was -- and I am not sure that that was even the thrust of it, that was the experience of it. But this study was designed to test, how do people feel about their knees? How were their knees working? How much flex did they get?

And Dr. Seng also analyzed -- there are these scores that people -- these ratings that doctors try to give patients -- or get patients to give them for their knees. They are called Knee Society scores, and there are different aspects. How is your knee working in your everyday life?

And Dr. Seng found two very interesting things. One is, he had the result saying that high-flexion knee has additional benefits for the quality of life in patients for patients who require higher degrees of knee flexion in their activities of daily living.

And then, the other thing he found was -- clinically, was that the Flex knee group did have 10 degrees more flexion. When you look at the chart in his paper -- because it was randomized. Everybody had the same average to begin with. And then the Flex group had a higher curve after surgery, and the non-Flex group had a lower curve, difference of about 10 degrees.

There are other studies that show there is no

difference.

As we have said before, we don't think this is really going to be an issue in this case. We didn't design these things to cause higher flexion. If they allow higher flexion, if these patients are experiencing higher flexion for some reason -- maybe it's because they are more comfortable with the knee, maybe it's because they are not getting rubbing or point contact. I have no idea. I am not sure that's been studied yet.

But I just wanted to point out that there is some data on both sides of that.

Dr. Lee had a similar study with comparing LPS and LPS-Flex knees. And what -- his finding was that people who had real problems with flexion before did a little bit better afterwards with a Flex knee compared to a non-Flex knee.

Dr. Scuderi. 141 patients. LPS-Flex. Two to four years. Dr. Scuderi's credibility was questioned in the prior presentation. I don't think that we are in a position to argue about people's credibility today. I think that that's something the experts will have to talk about.

THE COURT: No. In fact, I recognize there is going to be a lot of evidence about these very issues, statistical evidence about what did and did not work with the Flex knees.

And my focus today, which I think you have both

really accomplished, was to get a much better understanding of the technology. And I just think that's really useful.

There is a lot of advocacy that can happen here. We don't need to spend a lot of time on that, because I recognize that's going to be a matter of debate.

MR. YEAGER: Thank you.

So moving on from the papers.

THE COURT: Right.

MR. YEAGER: I didn't know where to put this slide because I don't know where the 5950 fits in, in our case, the MIS tibia.

THE COURT: I know it's your position it really doesn't belong in this case. But right now, it's here.

MR. YEAGER: Right now, it's here.

THE COURT: So you are welcome to go ahead.

MR. YEAGER: Just to give the Court a little technical information about where that comes from, there were -- that is the tibia that you have a sample of. There were some reports of loosenings. Zimmer did what it does, which is goes out and investigated those.

As a result, Zimmer changed the package insert and gave instructions to the surgeons and sent letters to the surgeons telling them two things.

Get the cement on there right. Get the cement all around it on the device and on the bone and make sure it's

all done because in some of the devices that had come out in these revisions, it looked like the cement had not been spread as perhaps it should.

And the second one was -- there is an optional drop-down stem that has a keel. The instructions said, to be safe, you ought to use the drop-down stem. That fixed the problem.

And second, the data for when there was an issue reveals no correlation to Flex. It happened with -- in fact, we don't even know what the femoral components were, whether they were Flex or non-Flex.

Knee development, testing, and regulatory processes, Judge, this is kind of just the tail end to give the Court an idea. As I talked about before, the knee designs come from prior designs.

How do we develop a knee?

Well, we start with what we have. We look at the data, the experience, the science from what we have. We have a design team. The design team has surgeons on it. And yes, sometimes you have to pay surgeons to be on a design team.

We all -- on these teams, we have external Ph.D.s and other technical experts, might be engineering, nonmedical experts. Internal to Zimmer, engineering, metallurgy testing, other disciplines. Obviously, we have a lot of expertise in the company.

They looked at the clinical performance of the devices. And as the devices are cleared for initial kind of limited release, they obviously watch those very closely after launch.

Testing. There have been some comments about testing in this case. We have laboratory testing. There is a facility at Zimmer where they take -- they have these large tanks where they have this fluid to simulate knee fluid. And they have rows of devices that -- they plant the prototype devices, and they simulate the function of the knee. And they just sit there and run all the time, many, many, many, many cycles. And they have the appropriate pressure on the knee and so on, so they can see how the knee functions.

They have millions of cycles overall. On the deep flexion alone on the Flex components, the deep flexion part of the flex cycle, we are told 225,000 cycles to make sure it works as it's supposed to work.

And I won't burden the Court with a detailed discussion of all of these kinds of testings, but there is a list that was in our written position paper:

Anterior liftoff testing to test the plastic surfaces in high flexion.

The contact area testing to make sure that you are getting the footprint. In fact, that was reflected in that chart.

Loading at the posterior edge of the tibial articular insert to make sure it would bear those loads for the life of the device.

Strength of the femoral component. Will it bear the loads?

And then the compression when you flex your knee between your kneecap and the femoral component. Make sure the device will bear those loads.

The articular surface spine, that's on the LPS device. There is a surface spine that bears some loads. Those are tested.

And then liftoff testing, meaning the plastic surface from the metal surface.

As I mentioned, there is an initial release phase. At that point, it's a permitted device. It's approved for sale. And then there is additional early patient scrutiny just to make sure all this testing and all the design hasn't missed something and it's something that doesn't turn up early on in implantation.

Just a quick note about regulatory process. The FDA dictates the process. We didn't choose to do the 510(k) process. The FDA tells us which process we have to use, and we have used that process, as every other orthopedic device manufacturer does.

We will give the Court a copy of this presentation,

but there is a Web site that the FDA has that explains this process. And what it basically says is that we make a submission to demonstrate to the market the device to be marketed is at least as safe and effective -- that is, substantially equivalent, not identical, not identical, not the same, substantially equivalent.

So the 510(k)s say, predicate device substantially equivalent. Here are the changes.

And then we get permission from the FDA.

So this is the end of the data. And we thought there were maybe three or four questions that these presentations leave open that we look forward to having answers for from the plaintiffs and from the experts.

What's the evidence of defective and unreasonably dangerous design? The claim is, there is a defect. What's the evidence of that defect in these devices?

As to the individual plaintiffs here, did their device fail? Some of these folks haven't been revised yet so we don't know if they really have a problem. Did their device really fail?

If they have been revised, why were they revised? Did the device fail in some way, or was it one of those many other reasons for revision?

Did the revision rates that are reflected in the data support the conclusion that there is a defect? They

seem to rebut the conclusion we think that there is a defect.

And finally, did the 5950 failures have anything to do with Flex? And why, in fact, were those folks revised? There were various reasons.

Unless there are any questions, your Honor, that's what we have for today.

THE COURT: That's great. Both of you, it's very, very helpful. It's exactly what I was hoping that we would do is kind of present the issues in a general way and specifically focus on this -- the way these things work. It's so much easier for me to visualize now than it was before this morning's presentation. So it's very useful.

I know we have a few other items on the agenda, and I am happy to turn to those now. In fact, where is my agenda?

MR. YEAGER: May I hand up a copy?

THE COURT: Sure.

(Document tendered.)

MR. BECKER: Your Honor, If you want to head through the rest of the agenda, I am hopeful it will take no longer than 10 or 15 minutes.

THE COURT: That's exactly what I was thinking.

MR. BECKER: Tim Becker on behalf of the plaintiff steering committee and lead counsel.

The parties submitted four additional agenda items,

three of which -- or two of which I think will be relatively noncontroversial; three of which I will handle, and one of which Mr. Millrood will handle.

THE COURT: All right

MR. BECKER: The first item on the agenda relates to third-party subpoena practice. I can report the plaintiff served, as the Court is aware, somewhere in the neighborhood of 12 to 14 subpoenas.

At the last hearing defense counsel expressed some concern that there was no prior notice given to the defendants. We have since remedied that. Defendants have received prior notice now of all subpoenas that have been submitted. And we are implementing a prior notice practice that before we even serve a subpoena, they will have prior notice of that subpoena in the event that they want to object and have any rights to move to quash.

With respect to the actual subpoenas that were at issue, as I understand it, there were two concerns that were raised by Zimmer. Both of those concerns have been resolved. Mr. Yeager and I had a conversation before the hearing today where he asked that we indicate on the record we will require, before the third parties produce confidential documents, that they agree to the court order, the order for protection that has been entered by the Court, sign off on that, and then produce the documents pursuant to that order.

And we have agreed to that.

THE COURT: That's great.

MR. BECKER: The only issue that remains is a cost-shifting issue -- or a cost-sharing issue, I should say. I am hopeful that we will be able to resolve that absent motion practice. But if we are not, we will simply bring it via motion practice and allow the Court to decide.

THE COURT: Okay. That's great.

MR. YEAGER: If I can be heard just briefly on that?

I think that's basically right. There are a couple of issues that we are going to continue to work on.

Just for clarification, the documents that come in from the subpoenaed targets not only are going to be subject to the protective order, they are going to be treated as confidential under the protective order until we agree or there is an order of Court.

Is that our agreement?

MR. BECKER: Yes. I mean, we have agreed until Zimmer has reviewed the documents that they will, for purposes of litigation, be treated as confidential. We may have a disagreement about whether or not the document is, in fact, confidential. But in the event we have that disagreement and are unable to resolve it via negotiation, we will come to you and ask for a resolution.

THE COURT: So they are presumptively confidential and subject to court order.

MR. BECKER: Correct.

THE COURT: That's fine.

MR. YEAGER: The other issue -- and I am not sure this is all the way worked out, but we probably don't need the Court's help just yet.

We think the subpoenas are this broad (indicating). They cover a lot of stuff that's not at issue in the case. We have had some discussion of that. Here is what's at issue in the case (indicating).

We are hoping to be part of the meet-and-confer. Obviously, we don't have to be a part of every conversation that may be had with the targets, but we are hoping to be part of the meet-and-confer.

The targets have all objected that the subpoenas were overbroad as well. So there is going to be a meet-and-confer process. It's either going to be resolved or it's going to come to the Court.

Zimmer's legitimate interest in that is simply that we don't get -- the protective order notwithstanding, we don't get this greatly overbroad production from these folks that we had professional relationships with.

Mr. Becker and I, I think, are pretty far down the road of getting that resolved. If not, we will come back

either personally or by motion.

THE COURT: All right. Great.

MR. BECKER: Let me just, if I could, your Honor, comment on that briefly?

As I understand the issue with respect to the scope of it, it relates to what products were requested in subpoena. The subpoenas specifically limit the products that are at issue or the requests, the scope of the subpoena to the products at issue in this MDL.

I think that we have, as Mr. Yeager indicated, gone a far way to clarifying that.

We have also agreed to provide notice to -- via letter to all of the targets to make sure that they are under the same assumptions as well.

Beyond that, he is correct that we have some issues with respect to whether or not they are going to be part and parcel of the meet-and-confer process with the third parties.

Anything else, Jay, on that?

MR. YEAGER: We are good on that for now.

MR. BECKER: All right. The next issue on the agenda, your Honor, related to document production. Unfortunately, here I think we have a considerably more substantive concern.

If the Court will indulge me, I would like to spend about five or six minutes just kind of relaying the status of

where we are and where we intend to go.

THE COURT: I do want to hear that, but I guess what I would like to do first, if we could, is talk about the issues where there are less disputes and then return.

MR. BECKER: Fair enough.

THE COURT: And I assume there is no large dispute on the joint proposed stipulation regarding the master complaint.

MR. MILLROOD: Your Honor, just briefly.

There is a couple of small issues relating to it.

THE COURT: All right.

MR. MILLROOD: Tobi Millrood for the plaintiff.

The parties have reached agreement as to the basic deadlines. Today, by the end of today, the plaintiffs will file a master long form complaint and a proposed form of short form complaint.

As to the master long form complaint, defendants are due to file an answer or response by February 27th under our stipulation.

As to the short form complaint, by a week from today we will either stipulate to have the Court approve the form only of the short form complaint or they will file an objection and we will take up practice.

The issue here that is germane to both of these is what we discussed last time as it relates to direct filing.

These two vehicles, the master complaint and the short form complaint, are relatively useless without direct filing.

And the reason for that is because there are going to be plaintiffs' counsel throughout the country that will have no real awareness. They are not members of the PSC. What they would have to do, practically speaking, is, they would have to file a complaint. Your Honor asked the question last conference if a short form complaint can be filed at the original district court. It cannot. I don't think it would satisfy the pleading standard. And ultimately the complaint comes back with the case.

A plaintiff has to file something in the originating court. And so they are going to be filing, essentially, three documents. They are going to file some form of complaint in an originating district court under the defendant's proposal. Then they would be transferred here. At which point they could adopt the master complaint and then file another short form complaint.

The way the short form complaint works in most of these product liability MDLs is, it's filed originally where direct filing has been adopted. Importantly, in direct filing the defendants are not deprived of any right. They still can come to the Court and say, this case doesn't belong here.

Now that the short form complaint has been written, it doesn't fall into the five categories that Mr. Yeager laid out before. And this Court is not divested of any kind of power to send it out if it doesn't belong here.

What it does is, it streamlines the process.

The Court has asked and the defendants have asked us to address as many comprehensive issues as possible in this master complaint. It's going to be voluminous because it has to cover every imaginable possibility as to all of these devices.

The short form really helps to simplify it. And if we don't have direct filing, there is really no point to the short form complaint.

THE COURT: Here was my thought. I am reluctant to allow direct filing in all these cases for a few reasons that I mentioned in a previous order. And now that everything is electronic, I am having trouble understanding why plaintiffs' counsel can't simply file in any other jurisdiction the long form complaint, the short form complaint, and a tagalong notice.

It's all electronic. You are not burdening any files. And I think it's clear -- it will be clear to the clerks of court throughout the nation, who are pretty sophisticated on this, oh, this is a case that's going to Northern Illinois.

MR. MILLROOD: Your Honor, practically speaking, that could happen. I think it's cumbersome for a few reasons.

First of all, there will be plaintiffs that are unaware of the master complaint.

THE COURT: But the plaintiffs that are aware of the master complaint won't know to file directly here anyway, will they?

MR. MILLROOD: Well, first of all, when they are short -- the number one question that we get from counsel that are outside of our PSC all the time, the first question is, is there direct filing, and is there a short form complaint available to us?

Now, yes, we could disseminate to all these counsel what's likely to be a 125-page master complaint with over 500 paragraphs, and they could all file that electronically, which is going to be over 13 megs, and file it in the ECF into each of those.

THE COURT: I really don't want to be difficult, but has anybody tried filing a short form complaint in the other jurisdiction and incorporating by reference the long form complaint?

Clerks throughout the nation have access to my docket. Why couldn't something like that be done?

It would just -- if we know which cases these are

coming from --

MR. MILLROOD: But, your Honor, if I may?

Doesn't that actually presume that the case belongs here anyway?

THE COURT: Sure.

MR. MILLROOD: Well, then, why not just direct file here? If you are filing --

THE COURT: I am concerned about this Lexecon issue.

MR. MILLROOD: Okay. The Lexecon issue is definitely a relevant issue. But again, it doesn't divest the Court of any power other than to preside over Northern District of Illinois cases, unless they waive it.

And it doesn't deprive them of the right to say, this doesn't belong here.

By the way, your Honor, I'd ask that you take a look at our proposed short form complaint, because what has happened at other MDLs is. The plaintiff has to plead in the short form complaint the jurisdiction from where this would otherwise have been filed but for direct filing and where it belongs upon transfer. So it treats the Lexecon issue.

That's the trend today by many of these MDL courts that are adopting direct filing. They recognize this Lexecon issue, and they put it directly in a short form complaint.

But for direct filing, this case would belong in

the district of Utah, the Southern District of Texas. And upon transfer, plaintiff consents the trial of this case there.

It just really, really streamlines the process. I can't emphasize it enough.

THE COURT: I am sorry.

(Brief interruption.)

MR. MILLROOD: So the Lexecon issue is addressed in our proposed short form complaint that will be filed later today. And I think perhaps before you reach a final decision --

THE COURT: Maybe I should look at that.

MR. MILLROOD: -- maybe you can take a look at that.

THE COURT: I will reserve on this.

MR. MILLROOD: Thank you.

MS. PIERSON: Your Honor, if I may, just briefly?

On this point of direct filing, there are a couple of ways that you described that a plaintiff can overcome this issue that Mr. Millrood mentions. One is for the plaintiff to file the master complaint in short form in the transferor court. The other is to file simply the short form.

As a practical matter, as long as defendants don't object to the sufficiency of the pleading, the matters are likely to be transferred to this court with no problem at

all.

And it seems very unlikely to us that any transferor court would be unwilling to transfer to this court following the filing of a master complaint, particularly one that incorporates the -- or excuse me -- a short form complaint, particularly one that incorporates the master complaint.

So there are easy ways to resolve this, as this Court has recognized.

And as a practical matter, what's happening right now, even without this process of master complaint and short form, is that the plaintiffs are filing a form complaint created by a member of the PSC that is largely identical from case to case. Those matters have been then transferred to the MDL, and the plaintiffs' lawyers can adopt the master complaint and the relevant portions of the short form. So this is not a particularly cumbersome process.

Even setting aside, though, the practicalities of it, there is a legal issue here. The legal issue is that Section 1407 and Rule 7.1 and 7.2 of the *Manual For Complex Litigation* give defendants the right to object to the transfer of these matters to the MDL. There is a particular process before the panel, as you know, where we have the right to object to the conditional transfer order.

And the defendants are unwilling to waive their

right to that process and to have the ability to object to the transfer of these matters.

The cases that Mr. Millrood mentions where direct filing is being used are cases in which the defendants have consented to that process. We are not consenting to that here. And we haven't waived our right to object to the transfer.

There are two key decisions that we cited in our papers on this issue many months ago, before the Court decided that there would be no direct filing. The *PremPro* MDL court and then also the *Norplant* court, both articulated the exact concerns that this Court has raised.

First, that you can't bypass the MDL statute on transfer without the defendant's consent. And second, that it places an unnecessary burden on this Court at the conclusion of the proceedings.

At the conclusion of these proceedings, we will file with this Court, if there is direct -- if there were to be direct filing, we would be filing motions to transfer to the correct venue. We would be explaining why under 1404 or 1406 these matters ought to be transferred to other venues. And there will be a fight in many of these cases, I predict, between the plaintiffs and the defendants as to the appropriate venue to which these matters ought to be transferred.

You and your staff ought not be burdened with that in 200 cases. Particularly when there is a statute that dictates the correct venue, the transferor court ought to be addressing those issues.

THE COURT: I have the submissions on this. I am going to take a look at the proposed short form complaint and see whether I have changed my mind. I can certainly do that.

All right. I think that leaves us with the issues of 30(b)(6) and the Zimmer document production.

MR. BECKER: Well, fortunately, the 30(b)(6) issue is really just reporting and not controversial at all. We served three 30(b)(6) notices, one on corporate organizational structure and history, one on information technology systems, and the third on -- loosely called it the 32 bullet-point deposition notice, which related to Exhibit A.

Currently, the corporate organizational deposition is happening on January 24th in Fort Wayne, Indiana. The IT deposition is going to likely happen between the dates, I believe, of February 6th to 9th in Fort Wayne, Indiana. And the third deposition was withdrawn under the hopes that we would be able to negotiate a resolution since it was largely related to document production.

THE COURT: Okay.

MR. BECKER: Which leads us into the final issue,

which is document production.

THE COURT: Right.

MR. BECKER: And here I think, Judge, at the last hearing you anticipated that there was a substantial document discovery dispute brewing under the surface. And unfortunately, I think that has reared its head at this point, and we are going to need some help from the Court.

Let me just take a few minutes to back up and kind of walk you through where we have been in the entirety of this litigation.

Long before the MDL was actually formed -- and by "long before" I mean almost six to nine months before there were cases that were individually filed throughout the country -- two of those cases in particular, a case involving a woman from Nevada named Kim Sizemore and a case involving a man from Minnesota named Ron Singsan, served written discovery requests. Those discovery requests were served on March 1st of 2011 and April 1st of 2011, respectively. They dealt with three of the five component parts in play in this litigation.

In November, after the case was transferred to the MDL court, plaintiffs' leadership, along with the plaintiffs' steering committee, served both interrogatories and requests for production of documents in approximately November of 2011.

Since that time, we have received under 20,000 pages of documents. At the last hearing or status conference, the Court itself noted that a 10,000-page production was described as minimal and requested three things occur.

One, that there be a substantial production.

Two, that the plaintiffs be encouraged to take depositions to identify, if any, chicanery was happening.

And third, that the current request for production of documents be held in abeyance.

It strikes us, your Honor, that if 10,000 documents in December was, as you described it, minimal, 9,934 additional pages can by no means reach anybody's understanding of what a substantial production is.

Yesterday I received a letter from defense counsel where we have made some progress in outlining what the scope of the 32 bullet points were that they identified.

There are a couple of things that are important in that letter that I want to note for the Court's attention.

The first is this: Number one, we have not had time to digest that letter, but we have serious concerns regarding the scope of the production itself in terms of what documents are being produced. I am going to go through that in just a minute.

One example, though, may be with respect to where

Mr. Yeager ended his presentation to the Court. We have never heard of simulation testing. We thought simulation testing occurred. He described it as millions and millions of sequential tests that go on, on a product-by-product basis.

The idea that that testing data is not comprised of tens of thousands of pages in and of itself simply defies credibility. And yet, we have not received that information. Or at least if it came, it came yesterday along with their additional 9,934 pages.

The second concern we have is that, candidly, the defense counsel noted, that we are halfway to completing production on the 32 bullet points. So what that means in practice is this: By March, the defendants will have had our Rule 26 disclosures, all of our authorizations for the originally filed cases, and the PFSs for those plaintiffs who were in the original wave of cases.

In other words, the defendants will have received the vast majority of documents for each and every one of the original 78 plaintiffs that were involved in this litigation, and we will have received less than 40,000 pages. That cannot be the way discovery is meant to occur.

So then we thought to ourselves, well, potentially what we have going on here is a misunderstanding. Let's delve into the documents, because, as you will recall, the

reason why Mr. Ronca endorsed the 32 bullets points was because maybe those would give us a guide as to how we could narrow or limit our document production.

Your Honor, if I may? May I approach to hand up a couple of documents?

THE COURT: Sure.

MR. BECKER: These documents are exemplar documents that we received from the defendants in their production. There are two sets of documents here that I would like to go through.

(Documents tendered.)

MR. BECKER: The first is a series of e-mails -- or we think they are a series of e-mails that were produced regarding the MIS tibial component.

Now, this document is relevant for a couple of reasons.

Number one, if you look at Page 1 and 2 of this document -- it's the five-page document that looks like this (indicating) -- the Court entered a protective order that expressly, over the objection of the defendants, concluded that internal redaction would not occur.

It is obvious from the top of this document that internal redaction has occurred because we have no idea who this document is from; we have no idea who it was sent by or where it was sent by. But we know it was sent by someone

because somebody is responding to another person.

THE COURT: Right.

MR. BECKER: So in and of itself, the document is in violation of the protective order.

The second thing that's relevant from these documents is this: Each and every one of these e-mails references a letter that was sent by Zimmer on December 17th, 2003. Yet nowhere in the production that they have sent, or at least that we have been able to locate, is there any discussion of what this letter actually is.

And finally, if you turn to the last page of the document, your Honor, you can see an e-mail from one of their doctors. Again, we have no idea who these doctors are, if they are paid consultants, if they are on the Zimmer payroll. But we know that this is an important document because what this particular doctor writes in commenting on the MIS tibial procedure in 2003, 2004 is, "Now about the implant itself. I like the concept of the shortened keel but not without the extension stem." He writes that in all caps. "Again, I don't have a strong feeling, but I will not use the mini keel without the stem for fear of loosening in the P.S. setting."

Now, your Honor, the reason discovery occurs -- and I am not breaking any ground here -- is so that we can find out what was actually happening in the company at the time these products were being rolled out.

This e-mail is written four years before -- I am sorry -- six years before the product was ultimately recalled for the very reason that the product was recalled. We are entitled to have an understanding of the facts and circumstances that are in a lot of these documents.

If you turn to Document 2, it's even more egregious. We received a document -- we have no idea where this document comes from. It's entitled "Z01029 CR-Flex Fixed Femorals."

I have no idea if this was created by defense counsel, if it was internally created by Zimmer. But what I do know is that there is a table of contents on the next page -- and in fairness to the defendants, all of the documents that followed 5.4 were actually attached. We just attached these two pages for exemplar purposes.

I have never seen a book, Judge, that starts with Chapter 5. We do not have Chapters 1 through 4. But even if this book were to start with Chapter 5, we don't have 5.1 to 5.3 or know what comes after 5.4.

We are nine months or a year, in some cases, into these cases. We are six months almost -- four or six months since transfer. To date we have no custodial evidence. We have no idea whether the defense has done an office-by-office search. And, in fact, we suspect they haven't because the letter that we received from them indicated they are waiting

for us for search terms, which we told them we would not give them, that we wanted to conduct documents in a traditional manner.

And I think you can tell from our presentation, your Honor, we are frustrated.

THE COURT: And I am frustrated, too. I guess I want to know what happened when you called them and said, look, we have got problems. You redacted material you weren't supposed to redact. You make reference to -- you provide us pages from a book that's obviously not complete. You have given us information about testing that should have happened long ago.

What happened when you called up the defendants and talked that over with them?

MR. BECKER: In fairness to the defendants, your Honor, I haven't raised these issues until today with them. But I can tell you this: I have had multiple meet-and-confers with them. I have repeatedly asked them over and over and over again, what is the scope of the production? What's the timetable that you are going to set?

We had a meet-and-confer less than a week ago where we finally agreed that they would give us some guidance on what the 32 bullet points meant. And we got that letter yesterday.

THE COURT: I know you want this resolved. No one

wants it more resolved than I do.

But I don't ever resolve discovery disputes where the parties haven't met. And I know you are going to tell me you have tried and tried and tried and it didn't work. I understand that's your position.

But if the concerns you are raising about these two exhibits, which are very significant to me, have never been addressed with defense counsel, it's meaningless for me to hold forth.

I think what we should do is this: I think you should meet with these people right now. They are here. I will see you at 5 o'clock this afternoon.

I am happy to resolve this. But I want it to be on an informed basis when you have had a chance to talk to them and they have said, no, we won't give it to you and here is why, so I know exactly where we stand.

MR. BECKER: Your Honor, if I may?

I am happy to meet with them, as I continued to do throughout this entire process, but we are meeting in a vacuum.

What we really want is this: We want to proceed with discovery. And the way we think that we can do that is twofold.

Number one, we would ask that you lift the abeyance or stay on the RPDs that were filed -- or that were served,

rather, on the defendants and make them provide us answers and objections to each and every one of those so that we can meet with them and discuss what they will provide.

THE COURT: I am completely willing to do that.

I will do that this second. I don't think it solves the problem, because I think you will be back here three weeks from now saying, Judge, here is our request. Here is what they gave us. Unacceptable.

And until you have talked with them about it, I can't make progress.

I am very sorry to hear you didn't get documents until yesterday. That makes it almost impossible for me to handle a discovery dispute intelligently, because you obviously can't have talked to them about the inadequacies of a set of 9,000 documents that showed up on your door yesterday.

MR. BECKER: Your Honor, that's the point of what I am trying to convey, is that you have a significant hammer here that you can assist us with. One of which is, you can say to them, answer the 200 RPDs. Because, if nothing else, that will give us a playing field from where we can identify where we have areas of dispute.

And whether it's an all-day conference in two weeks where I sit down with defense counsel, I can know the answer to the questions.

THE COURT: I am prepared to do that, but I can't do it based upon -- on a record where what you are telling me is, we got 9,000 pages yesterday and some of these pages are inadequate and unacceptable, unless those issues have been discussed with them.

Again, I will do it today. I am not stonewalling you here.

MR. BECKER: I know you are not, your Honor. What I am trying to indicate is this: Leave aside the issue of the sufficiency of the documents itself with respect to these two documents.

The issue that we have is this: There will be documents where mistakes occur, where something is redacted, where we don't think it was sufficient. We aren't even out of the starting gate yet.

You, last hearing, ordered them to produce a substantial production. We had a debate in a meet-and-confer as to whether or not the pages they gave us last Tuesday was substantial. Defense counsel took the position that the pages that they produced on Tuesday, which we received late Tuesday night, satisfied your order, and told us that unless there is clear guidance from the Court, they believe that they are in compliance.

If you look at the other MDLs that are going on right now regarding documents -- take, for example, the *DePuy*

MDL, there were 3 million pages produced in January alone.

THE COURT: If your point is that 20,000 documents is insufficient, point made. You don't need to convince me of that.

I have individual cases where individuals bring suits against individual defendants without hundreds of MDL proceedings out there where 20,000 pages is insufficient. There is no question in my mind that 20,000 pages is insufficient.

There is no question in my mind, based upon what you have said -- showed me and without hearing from the defendant, that there is a problem with some of the production that's happened before.

Come back at 5 o'clock. If you don't have an agreement, I will lift the restriction on your pending requests.

I think there ought to be a resolution of this, and I am disappointed that the documents didn't show up until so late that you couldn't have what sounds to me like any kind of a meaningful discussion about it.

If the defendants are telling you that they have completely satisfied my expectations, I will need to hear about that at 5 o'clock, because they haven't.

20,000 documents is obviously insufficient. Even without focusing on the content, it's just not enough.

MR. BECKER: Thank you, your Honor.

THE COURT: I will see you at 5 o'clock.

MR. BECKER: Thank you.

(A recess was taken at 12:20 p.m.)

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION,	)	Docket No. 11 C 5468
	)	Chicago, Illinois
	)	January 12, 2012
	)	5:12 p.m.

TRANSCRIPT OF PROCEEDINGS - Motions
BEFORE THE HONORABLE REBECCA R. PALLMEYER

APPEARANCES:

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THE CLERK: 11 C 5468, Zimmer NexGen Knee Implant Products Liability.

MR. FLOWERS: Hello again, your Honor.

Pete Flowers on behalf of the plaintiffs.

THE COURT: Good afternoon.

MR. YEAGER: Jay Yeager for the defendants.

THE COURT: Good afternoon.

Where do we stand?

MR. FLOWERS: We stand here, your Honor. We met for about two and a half hours this afternoon and, I think, came to an agreement as to how to proceed forward.

Real quick history, because I know you have been here a long time today.

THE COURT: I am fine. Take the time you need.

MR. FLOWERS: We, the plaintiffs, served requests to produce originally, a couple hundred. We then met and conferred and tried to come up with a solution that may streamline the discovery.

We worked on that over the last couple of months. And I think that has failed. From our perspective, we were concerned that only about 19,000 pages have been produced based on that.

So we met. We talked about a lot of things and have come to this agreement.

We would go back to the traditional discovery

approach. They would provide answers or objections or whatever is going to happen to the request to produce in 21 days.

We put interrogatories on hold for the time being.

We would then -- they would produce some documents -- we don't know exactly what, nor do they -- within that same timeframe.

And then we set up a tentative meet-and-confer for February 16th, subject to some scheduling of people that weren't in the meeting this afternoon.

Additionally, they are going to identify the documents and however they came to the conclusion that those documents are responsive to the requests. And we also had talked about an issue of trying to produce them potentially by a custodian that we are going to try and work out.

But that's the agreement we reached to try and move this whole discovery situation along and get us to a point where we are seeing documents. We can feel comfortable with that. They are producing what they can produce, and we move forward with this litigation.

THE COURT: All right. Mr. Yeager, anything you want to add?

MR. YEAGER: Your Honor, if I can take just a couple minutes?

I think Mr. Flowers has correctly summarized our

agreement.

When we left it this morning -- and I think we have gotten past a lot of this, but I think for the Court's benefit and, frankly, protecting my client, there were some pretty -- there were some stones thrown this morning at our production and at the number of documents we had produced and at some of the particular documents. And I just feel I can't leave that lie with the Court. With two minutes, I can explain.

Where we left this back on December 19th was that we were -- this was the phased process. We were going to produce in the 32 categories. The Court said in its order, pursuant to the party's agreement, produce those in 90 days and make a substantial production within 30 days, by today.

THE COURT: Right.

MR. YEAGER: We have worked hard on that. We have tried to follow the Court's order. And we thought we had produced more than half of those 32 categories by today. That's the additional 10,000 that made for 20,000 total in the 32 categories.

I think, to be fair, the plaintiffs thought that the 32 categories would encompass more documents. And I think there is some definitional misunderstandings about what the definitions were.

We were producing exactly what was in the

32 categories. We sent them a long list of elaboration on the categories, as the Court had asked us to do. That's why the number is what it is. Actually, we are ahead of the curve on producing those documents.

The rest of the stuff is sitting out in databases that are still being built up. There is as much as, and maybe even more, a terabyte of data, which I am sure the Court knows is an enormous amount of data. It's going to have to be searched. We have spent the afternoon talking about different ways that we might produce from that.

You can't have lawyers read every one of those documents. There would be millions. And I think the process that we have set forth is going to get us to that point.

The particular -- so that's the reason why the number of documents were produced that were produced. We were doing what the Court had ordered us to do, in our understanding, to go take those 32 categories and run them to ground and do what we could on them in the first 30 days. And that's what we have done.

On the particular documents that were discussed today, Ms. Butler can talk -- would talk about this for a moment. But they were produced exactly as they were kept in the files that were described in the 32 documents. They were part of design files and other files. They were not redacted. They were not taken out of context. They were in

the files as the people who ran the projects put them in the files. They would sometimes take fragments of documents and put them in there. Maybe the whole document exists somewhere out in the terabyte of data, and we will get to that in due time.

But we were not playing games. We were not pulling documents out. It was produced exactly as it was in the documents that -- among the documents that we were required to produce.

THE COURT: I don't think anybody suggested that there was some kind of cleansing of the documents that resulted in this concern about redaction.

The documents that were produced, as I understood it, made obvious reference to a letter that seemed to be important and that, I am advised, hadn't been produced. That would raise questions in anyone's mind.

And you are right that I ordered production within 90 days and defendants are then in technical compliance. I suppose what I should have done is said, 14 days prior to when you come in here, because it's really not workable for documents to be produced within a day or two or even three days of an appearance here and for me to expect that you will have had the conference that's necessary. And I am not in a position to rule on discovery disputes where that hasn't happened. I can't do that.

So one observation is that for these sessions to be productive, there has to have been -- the production of documents has to have occurred sufficiently prior to a court appearance, that plaintiffs' counsel is not handing documents up that you people haven't even looked at and no one has been asked to provide this December 20th letter, whatever it was. So that's just Point A.

If it's true that of the 32 documents, substantial production has been made, and that's only 19,000 documents, let's assume that I will accept that.

I would think that it would cry out for some explanation about why it is that, in light of the broad nature of these categories, so few documents actually fall into that group, because plaintiffs are clearly suspicious that it's not all there is. And your position is, of course that is all there is. And you need to explain why it is that plaintiffs expect so much more and, in fact, there really isn't any more.

I myself, on this issue at least, share plaintiffs' suspicion. It can't be that in a case like this, where we have got competent counsel on each side and where plaintiffs' original request for production was 200-some-odd requests that 19,000 documents is a substantial swatch of that. It just can't be.

In fact, you are telling me there is another

terabyte out there.

MR. YEAGER: Yes.

THE COURT: Time to be digging into that.

It's also time to be looking at the documents themselves so you can explain, when there are documents that make obvious reference to something else that's important, why that's not there, why that important whatever it is isn't there.

MR. FLOWERS: Your Honor, I just want to add one thing. This is a concern we expressed and will continue to express is, while we understand the defendant's problems producing what we believe is ultimately going to be several million pages of documents, we need to get those over some period of time where we can start to tell or expect what we are going to get, because to get to the deposition phase of this case, case-specific discovery, we need that stuff.

And we can't just be dropped with 5 million documents in May or in March or in April. We need to know in February, are we going to be getting 5 million pages of documents? If we are, fine. If it's going to be rolled out over a period, fine. But we need to have some idea of what it's going to be.

MR. YEAGER: And what we talked about in our meet-and-confer was, in response to that issue is, we will tell you as we produce -- it's going to be a rolling

production starting in 21 days. And we will tell you as we produce what we found and where we are in our searching of this large chunk of data.

For example, your Honor, you mentioned the letter that was referred to in a design history file, that someone had referred to in an e-mail that was in the design history file. If that letter still exists -- and I sure hope that it does -- it's probably out there in that terabyte, but it was not within the 32-document description, which was a very narrow description of very specific documents. That's why there are only 20,000 and probably maybe another 10 or 15 more. Who knows how many more.

But that's why it's a much smaller number, because it was crafted -- the 32 were crafted to be guide documents in specific categories. It's on a small subset of the 200 requests that we were served.

THE COURT: I am guessing your definition of a "design history file" and plaintiffs' is something different.

MR. FLOWERS: Yes.

MR. YEAGER: There is an FDA. I mean, there is a definition. It's a defined term, design history file, and we have to have certain things in it. And that's what we have produced.

MR. FLOWERS: That's why we are going back to the requests to produce, your Honor. That's exactly the reason

why we are going back to them, because we are not going to deal with this subjective determination as to what it is.

Every case I have been involved in, in medical devices, I get millions of pages. I don't care if it's one case or 10,000 cases, there's a lot more documents.

If they are saying there was 40,000 total documents for 32 requests, those 32 requests dealt with key issues in this case. And marketing, where's all the marketing material?

But that's water under the bridge, as I see it now. We are back to traditional discovery, and we will hopefully go forward with that. We will probably be back with some arguments, but we are going to try and work it out as best we can.

MR. YEAGER: And we put the 32-document process aside.

THE COURT: All right. That's fine.

Twenty-one days for the rolling production to begin.

I am going to direct further that there be -- that there be an attorney on each side who's the point person on discovery and that those attorneys have a telephone conversation at least every week, beginning 21 days from now, so that we get some sense of cooperation on this, because I am not sure that's happened.

I think there is good faith on both sides, but I am not seeing the kind of progress that should be happening.

I will put that in the order for today.

So when is our next meeting?

MR. FLOWERS: February 23rd, I think.

THE COURT: That sounds right. Okay. I will see you then, but that's obviously more than 21 days from now.

MR. YEAGER: Yes.

MR. FLOWERS: Right.

THE COURT: All right. Thank you.

MR. YEAGER: Thank you, Judge.

MR. FLOWERS: Thank you, your Honor.

(An adjournment was taken at 5:23 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Frances Ward January 24, 2012.
Official Court Reporter
F/j