TWO-LEVEL L4-L5-S1 AXIALIF
MT. SINAI MEDICAL CENTER
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00:00:11
WILLIAM TOBLER, MD: Good morning. This is Dr. Bill Tobler coming from Mt. Sinai Hospital in Miami Beach, Florida, where we are going to have a live broadcast of a minimally invasive spinal fusion surgery using the TranS1 technique. Could we go to the PowerPoint presentation? Dr. Jonathan Hyde -- Dr. Jonathan Hyde from Miami Beach, an orthopedic surgeon, is going to perform a minimally invasive operation using the TranS1 technique. I am from the Mayfield Clinic in Cincinnati, Ohio, and have had a large experience with the TranS1 technique along with Dr. Hyde. So I will be describing the operation as we proceed through the course of the surgical procedure. I'd like Dr. Hyde maybe to introduce the patient and discuss -- if we could go back to the live broadcast for Dr. Hyde to introduce the patient and to talk about the procedure.
00:01:27
JONATHAN HYDE, MD: Thank you. Welcome to Mt. Sinai. This is a 36-year-old laborer who's had a history of multiple back issues, multiple injuries, and unfortunately has a significant chronic back pain problem that has not responded to conservative treatments. He's had an MRI scan which demonstrates two levels of degeneration as well as an x-ray that demonstrates some early changes. He's had positive discography at L4/5 and L5-S1 with a negative control at L3/4. So this patient was indicated for stabilization of L4/5 and L5-S1. Bill.
00:02:04
WILLIAM TOBLER, MD: While Dr. Hyde begins to make the incision, I'd like to go to the PowerPoint presentation to just show you a picture of the TranS1 screw for L5-S1. The TranS1 procedure is a tit-- uses a titanium threaded screw that's inserted axially. It's inserted axially into the sacrum across L5-S1 to purchase both L5 and S1 in axial fashion. The unique feature -- very unique feature of this procedure is that there is absolutely no muscle dissection. The presacral fat pad is used as the quarter of access in a retroperitoneal approach to the L5-S1. It also preserves -- if we could go back to the camera -- it also completely preserves the annulus, the ALL, and the PLL, in contrast to the open ALIF approach, which is an inherently destabilizing procedure. Now, Dr. Hyde is making an incision lateral to the tip of the coccyx.
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JONATHAN HYDE, MD: So I've taken a mosquito clamp and I've just gone in at the lower coccyx region here. And I'm trying to keep my tip up so I stay on bone. Give me a shot of the fluoro, please. As you can see, it's curving up. Now, I'm just going to dissect a little bit here. And after I get up just a little bit -- x-ray -- I usually move to my -- Kelly clamp, please.
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WILLIAM TOBLER, MD: There is a air injected into the rectum so you can actually see air filling the rectum. Now, that will fall away as the dissection opens the presacral space. But you can see very clearly illustrated the presacral fat space that exists

between the front end of the sacrum, the front face of the sacrum, and the rectum. And that usually measures about one and a half to two centimeters in most patients. So he is bluntly dilating proximally in the presacral fat space, and this space will gradually dilate.
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JONATHAN HYDE, MD: Let's get an AP shot, please, before I move to the blunt dissector.
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WILLIAM TOBLER, MD: He does this under fluoro visualization. Can we go back to the PowerPoint presentation? So what you see here on the PowerPoint presentation is you see, on the left side, a mid-saggital MRI illustration showing an excellent trajectory into the L5-S1 space. On the far right side, you see an unusual but an abnormal sacral curve that does not allow the generation of a correct trajectory. Now if you go back to the camera, Dr. Hyde has taken an AP view and now continues to develop the presacral space. The presacral space up towards the mid-sacrum. Now he is passing the guide probe, which is a long, blunt instrument, and on the fluoro image, you can see the probe being walked up, gradually walked up the front of the sacrum.
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JONATHAN HYDE, MD: I kind of just wiggle it a little bit, kind of just keeping on the periosteal surface. X-ray.
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WILLIAM TOBLER, MD: The L5-S1 disc is in view, so he is also thinking about the trajectory into the L5-S1 disc space.
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JONATHAN HYDE, MD: Let's get an AP shot, see where I'm sitting at now.
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WILLIAM TOBLER, MD: Now we're going to take a look at the AP image in order to make sure that the trajectory is relatively in the midline as it projects up into the sacrum across the L5-S1 disc space and into L5.
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JONATHAN HYDE, MD: X-ray. X-ray.
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WILLIAM TOBLER, MD: As you can see --
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JONATHAN HYDE, MD: I go up pretty high. I actually go up to the promontory.
00:07:02
WILLIAM TOBLER, MD: Access approach can be done very quickly. So now he is in his mind's eye looking at where his entry point is going to be.
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JONATHAN HYDE, MD: So that's a pretty good dissection, I have to say. So, Larry, what I'd like you to do, I'd like to move the machine up so we can see the full vertebral body of L5. X-ray.
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WILLIAM TOBLER, MD: So now we're looking at the lateral spine and the sagittal balance. The lordosis that's maintained. I think that he goes high with that dissection just to help develop the presacral space.
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JONATHAN HYDE, MD: I do that. I've found in my experience that everything rolls a lot more smoothly and the final dilation and the final working cannula end up sitting much nicer when we do that dissection. X-ray. Okay, x-ray. That's a pretty good start point there.
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WILLIAM TOBLER, MD: People do have concern -- a question that frequently arises is what about the middle sacral artery?
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JONATHAN HYDE, MD: So once I get in, I'll drop my hand more.
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WILLIAM TOBLER, MD: Well, that middle sacral artery really drops off and is probably nonexistent at the roughly S1-S2 junction. He's going to enter the sacrum roughly the S1/2 junction. Now he's exchanging the blunt probe for a beveled cannula that he will actually drop into the periosteum. Now, he's just looking for his entry point into the sacrum.
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JONATHAN HYDE, MD: X-ray. X-ray. Okay, let's see what we have in the lateral shot.
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WILLIAM TOBLER, MD: Making final adjustments for his trajectory. So now he's looking at the final trajectory for his AxiaLIF procedure. He's tapping -- tapping the beveled cann- metal tip into the periosteum of the face of the sacrum.
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JONATHAN HYDE, MD: This guy's got conch bone.
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WILLIAM TOBLER, MD: Very firm, very firm bone. So now you can see on the lateral fluoro that the pin has advanced.
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JONATHAN HYDE, MD: I may want to bring it back a little bit. X-ray.
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WILLIAM TOBLER, MD: Going to make some final adjustments.
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JONATHAN HYDE, MD: Yeah, I'm going to just bring my start point a little bit more inferior in the sacrum, so let's go ahead and bring this back a little bit. X-ray, Larry.
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WILLIAM TOBLER, MD: He wants to move it a little bit more proximal.
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JONATHAN HYDE, MD: Okay. X-ray, Larry.
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WILLIAM TOBLER, MD: It's very important to make any adjustments or changes before you drill a channel into the sacrum.
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JONATHAN HYDE, MD: And it's key to go back and check your AP and your lateral shots as you're doing this because your trajectory is in both planes.
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WILLIAM TOBLER, MD: It's a little bit off the midline there, he's going to make a little adjustment. Tap.
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JONATHAN HYDE, MD: X-ray. Okay, let's see the lateral again.
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WILLIAM TOBLER, MD: Has a nice trajectory there on the AP. And the trajectory does not always have to be perfectly vertical.
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JONATHAN HYDE, MD: I like that much better, by the way.
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WILLIAM TOBLER, MD: A slight coronal tilt probably gives you a better fixation. Now you can see the sacral entry point is a little bit more proximal, so we've made that adjustment.
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JONATHAN HYDE, MD: X-ray. X-ray.
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WILLIAM TOBLER, MD: So he's -- he's --
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JONATHAN HYDE, MD: Well, you know, we may go in here, and then I'll use the -- you know what, I still think we need to go a little bit more distal on our entry point. Whoever's agreeing with me, thank you. X-ray. Okay. Okay, x-ray. Who's that, Fyler? X-ray. Shut up. X-ray. Okay, give me an AP shot, please.
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WILLIAM TOBLER, MD: So what he's doing, if you look back at the PowerPoint presentation, on the illustration of the -- if you look at the middle illustration, he's trying to find that sweet spot, that trajectory that will put him in an ideal -- ideal position. So let's go back to the live.
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JONATHAN HYDE, MD: He's got a slippery sacral... X-ray.
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WILLIAM TOBLER, MD: So he is very -- very firm-boned, so this is a very, very critical part of the procedure, because the whole trajectory of the operation is determined at this moment.
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JONATHAN HYDE, MD: X-ray.
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WILLIAM TOBLER, MD: Now he's got probably a very, very good trajectory. He's got a nice trajectory through the sacrum, not too far anterior, and a great trajectory across L5-S1.
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JONATHAN HYDE, MD: That's the only way to do it. When we do the drill, I'll have a much better --
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WILLIAM TOBLER, MD: Okay, coming back to an AP shot. Again, spending the time necessary to get the correct trajectory. Now he's advancing. He's advancing the guide pin into L5-S1. So now what you're going to see is the next step, is the final trajectory determination into the center sweet spot of the disc. He's got a very perpendicular approach into the disc space, which is ideal for placing all of the --
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JONATHAN HYDE, MD: Really good sclerotic bone.
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WILLIAM TOBLER, MD: Very good firm bone. Now the guide pin -- guide pin is advanced into the disc space.
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JONATHAN HYDE, MD: I'm going to dock that there. You know?
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WILLIAM TOBLER, MD: So now --
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JONATHAN HYDE, MD: Hey, Bill. Bill.
WILLIAM TOBLER, MD: Yes?
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JONATHAN HYDE, MD: Do you think this is a good two-level approach? What do you think? Take a look.
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WILLIAM TOBLER, MD: You have a very good -- yes, you have a very good trajectory.
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JONATHAN HYDE, MD: Well, let's see what we can do.
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WILLIAM TOBLER, MD: This could be for two levels. The trajectory is excellent for two levels. What we're doing now is we're putting an extender pin. This is the working channel. The procedure is performed over this guide pin. Now what we're doing is dilating a channel in the periosteum of the sacrum. So we have a series of three instruments. They're cannulated instruments with a 6, 8, and 10 millimeter dilator. The conical dilator is driven through the periosteum, so it expands the periosteum. He's taking out the 6-millimeter dilator and now he's going to dilate with the 6-millimeter dilator. He uses a little slap hammer, and that slap hammer is advancing, as you see on the fluoro, and it's nicely into the sacrum. Now he's going to remove the 6-millimeter -- 8-millimeter dilator, and now he's going to advance a 10-millimeter dilator that has a working sheath. This is the 10-millimeter dilator now that's being advanced with a rotational movement, always rotating the instruments along the 10. Now he's dilating the periosteum. And this is more difficult in a patient with very firm bones. So the conical dilator is being driven and expanding the periosteum and sacrum to determine the sacral channel. Now he's going to take out the inner portion of the cannula, so he's left with a 10-millimeter dilator. If we can take a lateral fluoro shot -- if we take a lateral fluoro shot -- can we take a lateral shot? -- we can see -- it's important to see the entire circumference of the 10-millimeter dilator docked into the sacrum. It needs to be circumferentially buried into the sacrum. Now he's using a 9-millimeter drill to drill a channel into the sacrum across the sacral endplate, but he's not going to touch -- he's not going to touch the L5 endplate at this point.
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JONATHAN HYDE, MD: Quick shot, Larry. Shoot.
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WILLIAM TOBLER, MD: Going to get an AP shot to see the trajectory and make certain that we have a good trajectory along the axis of the spine. Now he will harvest some of the sacral bone by removing the drill --
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JONATHAN HYDE, MD: Good sclerotic endplate. Oh, yeah. X-ray. I'm in. X-ray.
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WILLIAM TOBLER, MD: So now he's going to withdraw the drill in clockwise fashion, and there will be some autograft harvested from the flukes of the drill, probably about three to four to maybe even five cc's of very good autograft, and then there will be some [indistinct, overlapping] bleeding of bone marrow from the sacrum. So if we can get a look at that autograft. There's a few cc's of excellent autograft.
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JONATHAN HYDE, MD: So now we're going to take this 10-millimeter cannula out now.
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WILLIAM TOBLER, MD: Now what we're -- what we're going to do in order to accomplish a two-level AxiaLIF is to remove the 10-millimeter cannula. We're going to replace that -- we're going to replace that with a 12-millimeter cannula, which is the largest cannula. So we're going to dilate the sacrum from 10 to 12 millimeters. This will facilitate the two-level AxiaLIF procedure. Always maintaining -- always maintaining the trajectory with the pin. We'd like actually to have that pin --
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JONATHAN HYDE, MD: Nell, watch the pin, please.
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WILLIAM TOBLER, MD: -- slightly -- slightly engaged in the endplate of L5. So he's using the slap hammer, advancing the 10-millimeter cannula well into the sacrum.

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JONATHAN HYDE, MD: Okay, good. Perfect. Now I need the next drill.
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WILLIAM TOBLER, MD: So he's going to remove that, and then he's going to use the next size drill and he's going to drill the 12-millimeter channel. That drill actually is 10.5 millimeters in diameter. It's a cannulated drill.
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JONATHAN HYDE, MD: It's cannulated, so you can see the hole.
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WILLIAM TOBLER, MD: It's a cannulated drill, so we do it over the K-wire.
00:19:02
JONATHAN HYDE, MD: Okay. X-ray.
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WILLIAM TOBLER, MD: So he's advancing the 10-millimeter drill, so we'll have an 11-millimeter -- almost 11-millimeter channel drill --
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JONATHAN HYDE, MD: Now the wire's going to come out with me, okay? And just -- we've got more bone coming.
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WILLIAM TOBLER, MD: So we have a little bit more bone harvested, the wire -- the guide wire is being removed, because now we're going to use a series of cutters. These cutters are nitinol loop cutters. There's essentially four cutters of two different sizes. Two of the cutters are tilted upward so that we can scrape the endplate and the cartilaginous endplate off of L5. The two up-cutters are 10 and 15 millimeters in length, so he is using a 10-millimeter up-cutter, and you can see the cutter against the endplate of L5. He's now replacing that, and always doing that under fluoro with the 15-millimeter cutter. So you can see how long that cutter is anteriorly, and that's a little bit too long to take posteriorly because of the closeness of the spinal canal. So he works that high and low in the disc. This is a relatively tall disc. Right. We are morselizing the disc. So we're using these cutters to morselize the disc material, and then he will use a series of wire brushes. Those wire brushes will capture the morselized disc fragments. So we're essentially emptying the nuclear content of the disc --
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JONATHAN HYDE, MD: Hang on a second, Larry. Hang on a second, Larry.
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WILLIAM TOBLER, MD: -- to a diameter of about 30 or 35 millimeters, which really represents a large if not complete removal of the nuclear material in the majority of the disc spaces. Certainly some people have much larger disc spaces than others. Some discs are collapsed, some discs are very tall. And what we're doing now is he's getting an AP shot to look at the cutters on the AP views.
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JONATHAN HYDE, MD: X-ray.
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WILLIAM TOBLER, MD: And this -- this makes certain that you're staying within the confines of what you expect to be the volume of the nucleus. But then he'll use the two cutters that are the down-cutters, 10- and 15-millimeter down-cutters, to help morselize and remove the endplate.
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JONATHAN HYDE, MD: Yeah, I try to do this in quadrants, but when you have more posterior, you're actually kind of working in, like -- not even -- almost thirds, almost.
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WILLIAM TOBLER, MD: Right.

JONATHAN HYDE, MD: X-ray, Larry. Okay.
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WILLIAM TOBLER, MD: So now he's inserting the brush. He's inserting the wire brush. I don't know if you can see that brush on the fluoro, but you can see the bristles rotating and clearing out the disc, and you can see significant amounts of disc material that are removed.
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JONATHAN HYDE, MD: Okay, stop.
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WILLIAM TOBLER, MD: If we could go to the PowerPoint presentation, one picture that I'd like to show is an illustration -- an illustration of a volumetric discectomy that is achieved with this technique. If we can go back to live. Dr. Hyde is working the disc with the cutters, he's working the up and down cutters. He's going back and forth. I'd like to go back if we can to the PowerPoint presentation, and I'm going to show you a video of the discectomy. So this video shows the drilling, and now you see the -- the cutters working around the disc space, working in quadrants, evacuating the disc --
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JONATHAN HYDE, MD: One sponge in -- put the local bone in one sponge and the Formagraft. Just regular 5/1, this is the same surgery. X-ray. Perfect.
00:23:36
WILLIAM TOBLER, MD: And insert-- inserting -- inserting the brushes. Inserting the brushes and evacuating the disc material. Is that coming through on the PowerPoint? Good. If we can go back to the live video. Live video.
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JONATHAN HYDE, MD: Give me a large down. Large down. X-ray.
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WILLIAM TOBLER, MD: So you can see the --
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JONATHAN HYDE, MD: I'm feeling some good scraping. X-ray. Go live.
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WILLIAM TOBLER, MD: You can see him removing the disc material, morselizing the disc material with the down-cutter there. I think that's the -- is that the large down-cutter?
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JONATHAN HYDE, MD: This is the large down-cutter. And what I do is --
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WILLIAM TOBLER, MD: If you can show the lateral -- straight lateral so we can see what that looks like.
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JONATHAN HYDE, MD: See it's kind of angled down there?
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WILLIAM TOBLER, MD: Now you can pull the cutter back a little bit and straight -- you can scrape the endplate.
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JONATHAN HYDE, MD: I think that's the key. I mean, it's all about preparation of those endplates. If you don't do the job, it's not going to fuse well.
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WILLIAM TOBLER, MD: And manipulating -- manipulating the cutters to reach the various portions of the endplate. Now he has a brush in there. If we can go back to the PowerPoint presentation, this is an illustration -- this is an illustration of the amount and the volume of discectomy that can be removed. In the lower right-hand

corner, you can see large pieces of cartilaginous endplate that have been removed. If we can go back to the live camera.
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JONATHAN HYDE, MD: And these work only when you use them in a counter-clockwise fashion. That's the way these extractors are designed. Well, part of the feel is with the curettes, and you can feel the scraping. And in a quiet room, without all the cameras and everything, you can actually hear the scraping, and it almost works -- you know, it's a solid structure, so we actually feel the vibration change as you're working.
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WILLIAM TOBLER, MD: This -- this operation -- remember --
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JONATHAN HYDE, MD: So there's not much left here. We've really cleaned it up, as you can see. As we've gone from -- this is probably like my fifth or sixth one -- you can see that the volume has changed. And now we've got basically nothing. I'm going to put one more in as a final.
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WILLIAM TOBLER, MD: Keep working the disc until it comes back empty.
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JONATHAN HYDE, MD: So as I've been doing this, my PA, Melissa, has been working on packing the graft tubes, and my pack that I'm using on this case is the local bone from the drawing through the sacrum. I also use some Infuse. I also take some of the BNP from the Infuse and I kind of infuse that into some Formagraft to add as a bulking agent. And there's really nothing left here. So you got the stuff? There you go.
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WILLIAM TOBLER, MD: So one of the things that Dr. Hyde is talking about while he's inserting the bone graft material is the tactile nature of this operative approach. The cleaning of the disc with the nitinol cutters is extremely tactile. Now, he has the bone -- the bone inserter, which has a beveled tip. That bone inserter can be directed circumferentially around the L5-S1 disc space. If we can go to the PowerPoint presentation. Here is an illustration showing the packing of the bone graft material of your choice into the disc space. And we pack that in quadrants circumferentially around. The -- as we were talking about the tactile nature of this operation, you're never directly looking at the operative field. It is all done on the camera using biplanar fluoroscopy, tactile sensation, and also feeling and hearing what you're doing with the cutters, scrapers, and final insertion of the TranS1 screw. More bone graft material is being inserted.
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JONATHAN HYDE, MD: Pick up. I always keep my fingers so nothing falls out at the end of the hole here.
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WILLIAM TOBLER, MD: Packing more graft material.
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JONATHAN HYDE, MD: This is the bulking agent. I've already put in the local bone. I've also put in one sponge, and this is actually a second sponge I've infused for later. And actually, this is the Formagraft, where I've actually had some of my extra BNP I kind of mix with it. And it really adds to the bulking of this. Sometimes I will use some allograft and sometimes I'll actually use some autografts as well from the crest, it depends on how much fill I need to do here. But we're almost done with the fill. I could fill the difference in the actually quality of the pack. X-ray. And you can see on the x-ray, if you look on the fluoro, you can start seeing, it's getting darker. A

little bit more radio-opaque in front of it. You see that? Okay, so now what I want to do is get me that 10-millimeter drill. The drill. The drill that I used, okay?
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NURSE: The 10.5 or the 9?
00:28:51
JONATHAN HYDE, MD: The 10.5. And then what I'm going to do is I'm actually going to turn this counter-clockwise and use this to pack all my grafting material out of where I'm working. X-ray.
00:29:00
WILLIAM TOBLER, MD: So he's going to circumferentially push the graft material and now create -- create the channel into L5.
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JONATHAN HYDE, MD: And packed it really nicely in there, okay? So I like that. So now we've really done what we need to do at this level, so what I'd like to have -- give me this part. Thank you. And we're going to drive this down a little bit more now. X-ray. Okay. X-ray.
00:29:33
WILLIAM TOBLER, MD: So he's driving his 12-millimeter cannula deeper into the sacrum. And you can see the projected trajectory across L5, and we'll have an excellent, excellent trajectory into the L4/5 area.
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JONATHAN HYDE, MD: X-ray. Perfect. Now I'm going to -- hang on. X-ray. No one likes when I do this, but this is what I'm doing. X-ray. X-ray.
00:30:14
WILLIAM TOBLER, MD: He's driving -- he's driving the end -- the cirumferential in its entirety so that it's purchased across the endplate of S1 but not into L5.
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JONATHAN HYDE, MD: This is not what I need. Give me my -- give me that -- the dilator. This is exactly what we were talking about the other night. Well, my European colleagues were correct about this piece. Okay, do you have another 12-millimeter tube?
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NURSE: Yes, we do.
00:30:50
JONATHAN HYDE, MD: Another 12-millimeter tube. I'm going to exchange this out. Okay, guide pin, please. Guide pin. Okay. X-ray. It's okay.
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WILLIAM TOBLER, MD: We're going to switch out the 12-millimeter tube.
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JONATHAN HYDE, MD: Okay, I need... Bill, why don't you talk for a minute?
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WILLIAM TOBLER, MD: Yeah, what I -- what I'd like to do is talk about the experience that we've had in Cincinnati. We first performed this procedure almost three years ago in June of 2005. And we have -- we've evaluated very carefully our experience in about 190 patients now that we have treated with the TranS1 technique at the L5-S1 level. The -- we have -- we have looked at outcomes in terms of VAS and ODI, and importantly, we've evaluated our complications and our follow-up at one year with ODI and VAS, including thin section reconstructed CTs. Now, in our series -- and everybody has a concern -- everybody has a concern about the safety of the approach. We've only had one approach complication in almost 200 cases, and that was a laceration of the bowel. And I think that some of the techniques we've introduced have helped to minimize the risk of any of those complications: injecting air into the bowel prior and even at the end of the

procedure, if you wish, you can check the integrity of the bowel by injecting contrast material into the bowel. And also, I think that it's important to have a relationship with the colorectal surgeons, who know -- who know what you're doing with the TranS1 procedure. Suspected bowel injury could be diagnosed and treated prospectively with keeping the patient NPO, IV antibiotics for a few days. And most small lacerations will heal on their own. So it's important to be aware of that, because if you have an unsuspected bowel injury and you wait until you have a -- have an infection -- you wait until you develop an infection, then you have to operate on the patient's brain, the abscess, and then treat the patient with a temporary colostomy. So that's what occurred in our one -- in our one patient. And that was treated successfully, the disc space never became infected, and his colostomy was reversed. So we've had no other -- no other approach complications. We've had one or two draining wounds that drained for a couple days and were treated with antibiotics but never really became grossly infected. There have been no device failures. We've had no neurological injuries. The presacral space -- the presacral space is very devoid of vascular and neural structures. There's about a distance of four to six centimeters between the neuroforamina.
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JONATHAN HYDE, MD: X-ray. Okay, we'll be okay.
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WILLIAM TOBLER, MD: So Dr. Hyde's readjusting the 12-millimeter --
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JONATHAN HYDE, MD: I got it, I got it, I got it. I've just got to -- X-ray.
00:34:48
WILLIAM TOBLER, MD: Could you say that again?
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JONATHAN HYDE, MD: This bone is so hard.
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WILLIAM TOBLER, MD: Well, the -- our entire experience, we've had one major complication. We had one patient --
00:34:59
JONATHAN HYDE, MD: This guy's bone is so hard, there's no way I'm going to bring this up any further.
WILLIAM TOBLER, MD: -- who had a bleeding disorder, a familial coagulopathy. And he had a pulmonary embolism, DBT -- he had two post-op. And that was treated without any complications. But the overall worldwide experience with the TranS1 procedure also confirmed a very low rate of complications. And of course, the major feared complication is the risk of bowel injury, but statistically, it's less than 1%. So it has been proven repetitively in different centers that the approach is very safe when appropriate -- appropriate measures are exercised. What we're doing now is drilling through the body of L5 with the nine-millimeter drill into the L4/5 disc. And he has a beautiful trajectory across the L5 vertebral body. Were going to check that on an AP view. We have excellent, excellent trajectory. So we're going to go back to the lateral, he's going to withdraw, he's going to get -- harvest more autograft, more autograft, large amount of autograft -- we can show that on camera. There's a good five cc's -- five cc's or more of additional autograft. So now we're repeating -- repeating exactly the same procedure, advancing the nitinol cutter, the loop cutter. That's the up-cutter 10-millimeter, rotating it around the disc space. And again, we're going to check -- check the laterality of the cutters to make certain that they're within the confines of the nucleus at L4/5.
00:37:14
JONATHAN HYDE, MD: [indistinct]
00:37:42

WILLIAM TOBLER, MD: Okay. So do we have that AP fluoro shot? You can see him rotating with a long cutter. So he's got excellent circumferential access on the AP off to the left, off to the right. So he's got a great access into the L4/5 disc space. So now we're going to go back to the lateral. Sometimes there is disc material that comes out with the nitinol cutter. Now he's advancing the next cutter up into the L4/5 disc. He's employing the cutter, down-cutter. Now he's scraping the endplate. Scraping the endplate of the top of L5. Rotating -- what I'd like to -- what I'd like to show here is a little bit of fusion outcomes. We have categorized with an independent neuroradiology our classification of fusion. And if you review the literature, the literature is not clear and there's not a uniform definition of fusion in the literature. But we're using high-resolution thin-section CT to document maturing and advanced fusion, which is a predominance of bridging bone across 50% or more of the available space. Evolving fusion would be somewhat less than 50%. And no fusion or pseudarthosis is no evidence of any bridging or developing bone, associated with halos or evidence of loosening of the TranS1 device and/or the facet pedicle screw construct posteriorly. The intermediate category of developing bone is a condition where we identify developing bone within the disc space but we don't see bone bridging from one endplate to the other. So we've very carefully evaluated our fusion results. And what you see here is a very nice immediate post-op picture of a patient treated with Infuse and Vitoss as the graft extender immediately post-op. And then on the right upper-hand corner, you can see a solid arthrodesis. This is at one year, and this is of course a very ideal outcome. The next slide shows a progression of six months to one year, and then the next one is another mature fusion. So we'll go back to the live video. And we're still cleaning out the disc space, and you can see here, he has the down-cutting loop cutter. And this tactile part of the procedure is important, because if there are irregularities in the endplate, your cutter might get -- might get trapped. And if you force-- forcefully rotate your cutter, you could snap the cutter. John is evacuating more disc material from the L4/5 disc. Series of brushes. Sometimes we use eight to ten or even twelve brushes to thoroughly evacuate the disc. We go back and forth and cycle the cutters multiple times, scrape the endplates. Now he's putting the large up-cutter in again. He's going to push it against the endplate of L4 up, so you manipulate those cutters, you begin to feel the endplate, and you hear the endplate. You hear the scraping against the endplate. Going to go back and look at an AP view, he's got a brush in place. So this is a step -- you don't need to hurry through these steps of the procedure. Be very slow, deliberate, always keep your eye on the fluoro image. Couple of brushes. Now he's removed the brushes, put the cutters back in. Working the disc on the left, on the right. Advancing the brush, and you can see the bristles on the brush rotate around. I think you can see that live on the camera. It's sometimes hard to see, but this is a very good fluoroscopic image. Another brush. He still is retrieving disc material. So we'll leave no disc material behind, get it all out, and you can actually feel -- there's a picture -- I don't know if you can get that, but there's a little endplate, a nice piece of endplate on the cutter, or on the brush. And as you evacuate the disc, you can feel the resistance, the rotational resistance as you rotate those brushes and cutters, you can feel it diminish until you eventually have an empty disc. So back and forth, he's cycling the cutters numerous times, making certain that the cutters are always within the confines of the disc space.
00:44:18
JONATHAN HYDE, MD: X-ray. You can hear me, guys? Oh, my God, you fixed the battery. I hope you use Duracell. X-ray.
00:44:38
WILLIAM TOBLER, MD: So I think he's probably about finished.
00:44:39

JONATHAN HYDE, MD: I'm about done. I'm just going to finish up the whisks I have.
00:44:41
WILLIAM TOBLER, MD: I'm sure that you can feel the endplate, you can feel the clean endplate.
00:44:46
JONATHAN HYDE, MD: You can absolutely feel it, but still there's a little bit left. I'm just going to take my time, clean that out as much as I can.
00:44:52
WILLIAM TOBLER, MD: He's cleaning out the disc space.
00:44:55
JONATHAN HYDE, MD: Now, I opened up these whisks, might as well use them all and make sure I really clean that up significantly.
00:44:59
WILLIAM TOBLER, MD: Now, sometimes what you see on patients who have more degenerative collapse than this patient, you can see that as you remove the disc that you're actually -- you're actually destabilizing the segment a little bit. And sometimes during the course of the procedure, you actually see some spontaneous restoration of disc --
00:45:22
JONATHAN HYDE, MD: Good chunks coming. X-ray.
00:45:29
WILLIAM TOBLER, MD: Well, as -- right, as I mentioned earlier on in the presentation, that this operation does not destroy any of the annulus, any of the ALL or the DLL. The open ALIF is a destabilizing procedure, and you resect essentially all of the ALL and a large portion of the anterior annulus. So -- so this operation does not create more destabilization on the way to achieving arthrodesis. So now what he's doing is he is inserting his disc material through the bone inserter, the beveled bone inserter on the fluoro right now. So if we could get a fluoro shot, you can see how he can rotate that. Will you rotate that around, John, so you can --
00:46:28
JONATHAN HYDE, MD: Yeah, go live.
00:46:29
WILLIAM TOBLER, MD: Go live and you can see how that bevel rotates so that it directs -- it directs the insertion of the bone graft material.
00:46:38
JONATHAN HYDE, MD: We'll be okay. We'll probably end up using one of the smaller ones, but it's going to give us some good lordosis with the angles that we're working on.
00:46:46
WILLIAM TOBLER, MD: What we're doing right now is looking at -- we're looking at some of the trajectory and making certain that we have good lordosis preserved. The positioning of the patient is very, very important because they're going to be fused in the position that they're in. So we have good lordosis here. Dr. Hyde is continuing to direct his bone graft material, and I'll tell you, some of these cases, you can -- you're inserting 10 to 15 cc's of autograft and allograft into the disc space.
00:47:29
JONATHAN HYDE, MD: We're right in the middle, so you can go deep on that, too, actually.
00:47:32
WILLIAM TOBLER, MD: Can we go back to the PowerPoint presentation? What you see here is a very solid fusion one year out in a patient who had severe degenerative disc disease with posterior stabilization using facet screws. And you can see that the TranS1 screw is entirely bedded in solid fused bone. It almost looks as if there was a

disc space never present to begin with. But also on the AP, you can see that the -- this TranS1 screw is offset in the coronal plane. This is actually probably more favorable to stabilization of the disc space, given the knowledge we have of the central axis.
00:48:19
JONATHAN HYDE, MD: I'm just packing the bone with the nine-millimeter drill bit. Let's go for a 7.5.
00:48:22
WILLIAM TOBLER, MD: -- and the placement of -- we'll go back to the live. So the L4/5 disc has been packed. Now we're drilling into L4, into the body of L4. And the endpoint is about 75% distal into the body of L4. Now, what we're doing -- what we're doing now is magnifying the fluoro, and we're templating. We're templating for -- for choosing the sizes of the TranS1 screw. Now, we haven't discussed this very much, but for two-level -- the two-level axial effusion, we have -- the TranS1 screw is actually a two-component screw. Into the L4/5 level, we're going to insert -- we're going to insert a long screw that's between 50 and 60 millimeters in length. Then we dock the sacral portion of the screw into that. So we'll talk about that a little bit more, but what we're looking at -- what we're looking at now is our trajectory on the AP and the lateral, and the trajectory into the body of L4 is anteriorly and directed toward the corner of the anterior part of the top of L4. And that's a very strong area of the vertebral body for the tip of the screw to be lodged.
00:50:16
JONATHAN HYDE, MD: X-ray. Okay, I'm going to do some different measurements here, okay? Magnify it, Larry. X-ray. Okay. X-ray.
00:50:26
WILLIAM TOBLER, MD: So I'd like to show you the PowerPoint presentation while he's taking some -- so what you see here on this side is the two-level device. The two-level device is shown on the right side where it's assembled, and it's actually two components, the sacral component that you see on the left side that's anywhere from 25-30 millimeters in length. And then the L4/5 component. The L4/5 component we call the A and B component. The sacral component is the C component. So now if we go to the next slide.
00:51:11
JONATHAN HYDE, MD: So what we're doing, we're templating, and for this type of two-level procedure, you template off of the L5 vertebral body. That's actually the critical part of measurement for the implant that goes in. I'm measuring about 22 and a half right now. I'm going to it one more time. X-ray.
00:51:35
WILLIAM TOBLER, MD: So we're taking a measurement -- the first measurement is to measure the height of the L5 vertebral body.
00:51:41
JONATHAN HYDE, MD: One, five, ten, fifteen, twenty -- 22.5 I'm getting. So you want to go 25? I'm thinking 25 so we have a little bit prowed. Let's measure our full length of the whole thing. X-ray.
00:52:02
WILLIAM TOBLER, MD: We have three choices for the vertebral body height of L5: 25 millimeters, 27 and a half, and 30. So he's taking that measurement now.
00:52:16
JONATHAN HYDE, MD: One, two, three, four, five, six, seven, eight, nine, ten, fifty.
00:52:24
WILLIAM TOBLER, MD: That's correct, it's very -- the 4/5 screw really looks like the 5/1 screw. It's a little bit different in size. And then the S1 component is inserted.

Right, if you look at the fluoro, we're templating -- we're templating the length of the screw into L4/5 and to L5-S1. So these templates help us to make the decision.
00:53:00
JONATHAN HYDE, MD: We've been deciding whether or not to use a 50 millimeter or 55 millimeter implant. The thing which is nice when you have a little bit prowed into L5-S1 , it actually gives us the ability that we can get a little bit more distraction there, and I really think that a 55 may be a little bit better than the 50, so let's go with that right now. And we're not going to use the big distracter one on this, we'll use the medium distraction.
00:53:22
WILLIAM TOBLER, MD: So there are two different thread pitches on the L4/5 screw that will give us some distraction. It's thread counts per inch, and we have a possibility of two different combinations: 10x11 thread count pitch, and that's 10 -- 10 -- or 10x12. The 10x12 differential thread count gives us a little bit longer length. So what we're doing now is we are removing -- we are moving the 12-millimeter cannula. So we have our light blind, that Steinman pin that's left in place, and the screw has to be inserted through a larger tube. So we are using what we call the exchange cannula. Can we go to the -- can we go to the PowerPoint presentation? What you're seeing is the insertion of the exchange cannula, and the center cannula's removed, and so this -- this -- this creates a press fit almost to the front of the sacrum. So it allows us to advance the screw and make certain that none of the presacral fat or other contents can get ensnarled in the insertion process.
00:55:04
JONATHAN HYDE, MD: Okay, that's great. Okay, let's go for the 30. And you've got the K-wire and the K-wire driver ready, please. Excellent.
00:55:11
WILLIAM TOBLER, MD: So we actually have two different cannulas, one that's 30 degrees and one that's 45, based upon the angle of the sacrum. And you'll see how that fits as he advances that. Now I want to talk a little bit about the screws that are going to be inserted. All the screws are -- are created that they have an inner and an outer diameter. What -- what the outer diameter of the screw is is the measure of the outside of the threads.
00:55:47
JONATHAN HYDE, MD: I'm just locking the working cannula into the sacrum so it doesn't migrate or rotate on me. X-ray. And we're going to bring it a little bit more so you can see it. X-ray.
00:55:57
WILLIAM TOBLER, MD: He's got a little wire that he's docking. He's docking the exchange cannula.
00:56:05
JONATHAN HYDE, MD: X-ray. You can see it. It's pretty clear, I'm looking at the fluoro from a pretty long distance and I can see that here. Okay.
00:56:13
WILLIAM TOBLER, MD: Could you point that out on the fluoro?
00:56:16
JONATHAN HYDE, MD: Okay, do you have the first bolt ready? Okay, okay. Get the screwdriver for it.
00:56:23
WILLIAM TOBLER, MD: So just to finish up the comments about the internal and external diameters of the screws, they're basically slightly larger than the channel that we drilled, so --
00:56:33

JONATHAN HYDE, MD: Tom, move your hand. Move your hand here. Just hold it on the other side.
00:56:37
WILLIAM TOBLER, MD: As the screw is threaded into each component of L4/5 and S1, there's a press fit.
00:56:45
JONATHAN HYDE, MD: Okay. Okay, hold this here. Hold that here. Okay.
00:56:48
WILLIAM TOBLER, MD: Okay, now the inner -- the inner cannular stylet is being removed. So the L4/5 component -- can we show the screw before it goes in?
00:57:00
JONATHAN HYDE, MD: Okay.
00:57:03
WILLIAM TOBLER, MD: So there is the 55-millimeter screw being threaded down -- down the Steinmen pin.
00:57:17
JONATHAN HYDE, MD: Perfect. Okay, x-ray.
00:57:22
WILLIAM TOBLER, MD: So now you're going to see, the screw is going to be advanced, the A and B component of the screw are being advanced through the 12-millimeter sacral channel along the Steinman pin, across L5-S1, and then into L5 vertebral body. And there is a firm resistance that you feel because of the press-fit nature of the insertion process, and it will be compacting the bone, it will be compacting the cancellous bone as it goes in.
00:58:03
JONATHAN HYDE, MD: X-ray. X-ray. X-ray.
00:58:09
WILLIAM TOBLER, MD: Now we're advancing --
00:58:10
JONATHAN HYDE, MD: Barry, x-ray. X-ray. What's going on with x-ray? We have to reboot x-ray for a second, guys.
00:58:18
WILLIAM TOBLER, MD: Okay.
00:58:20
JONATHAN HYDE, MD: Reboot it?
00:58:23
WILLIAM TOBLER, MD: We're burning -- we're burning up this fluoro machine here.
00:58:26
JONATHAN HYDE, MD: There's a lot of equipment in this room. The room is extremely hot.
00:58:29
WILLIAM TOBLER, MD: Yeah, we're not really using an excessive amount of radiation, but we are -- we are using a lot of heated instrument and there's a lot of generation of heat. Well, the indications for this procedure are for degenerative disc disease at L5-S1 and now at L4/5. And actually, degenerative disc disease also would include spondylolisthesis. Spondylolisthesis at either 4/5 and 5/1. We have had an extensive experience with successful stabilization with spondylolisthesis. Because of the biomechanical forces with the spondylolisthesis, it is an excellent biomechanical solution for the sheer forces across the disc space. The TranS1 screw has a purchase across the disc space unlike any other interbody device. Most of those interbody devices are simply wedged into the interspace and depend on ligament ataxis, at least what's left of the ligaments, to support you. So it's essential, though, that the sagittal alignment be restored in order to drive the screw into position. So now on

the live fluoro here, if you go back to the live fluoro, crossing the L4/5 disc space. The goal is --
01:00:05
JONATHAN HYDE, MD: Larry, I want you to magnify for me, because I need to see the base of 5 when I'm doing this part now. X-ray.
01:00:11
WILLIAM TOBLER, MD: The goal will be to leave a couple of threads prowed across the endplate into the disc space at L5-S1.
01:00:20
JONATHAN HYDE, MD: Maybe a half a turn? What do you think, Matt? X-ray. That's it. Okay. So now hold the wire.
01:00:33
WILLIAM TOBLER, MD: Sometimes you can -- you can actually disengage -- you can disengage the inserter mechanism in order to see where the threads are. He can reengage it easily. Can we take a lateral -- another lateral fluoro shot? So now you can see -- actually, you can -- you may have to fishtail your fluoro a little bit to make sure you're looking flat across -- flat across the endplate at L5.
01:01:03
JONATHAN HYDE, MD: So now we know we have a deep sacrum, so there's a 25 and a 30. I've opted for the 30, because I already know I have a very long tunnel. So this is actually going to hook in. It's almost like tapered, and actually -- will actually add to distraction once it hooks in.
01:01:22
WILLIAM TOBLER, MD: There's the 30 -- he's inserting now the 30-millimeter C part for the sacrum part of the screw. Over the guide wire, see the good video.
01:01:41
JONATHAN HYDE, MD: Yeah, we'll just bring that back in a second. X-ray. X-ray. Okay, x-ray. Okay.
01:01:47
WILLIAM TOBLER, MD: Always watch --
01:01:48
JONATHAN HYDE, MD: Give me a Kocher, I want to just pull this wire back a little. X-ray. X-ray.
01:01:58
WILLIAM TOBLER, MD: What he's -- what he's doing is just watching the guide wire. He's withdrawing the guide wire.
01:02:05
JONATHAN HYDE, MD: X-ray.
01:02:08
WILLIAM TOBLER, MD: Now, it really firms up, because the outer -- the outer diameter -- the outer diameter of the C section is significantly larger. It's approximately 15 and a half millimeters, so there's a real tight press fit into a channel that's drilled that's 12 millimeters in diameter. You can see, he's working pretty hard to get that. He's watching the K-wire. Stabilizing -- the assistant is stabilizing.
01:02:53
JONATHAN HYDE, MD: Yeah, x-ray. Can you just magnify that?
01:02:58
WILLIAM TOBLER, MD: Continue to watch the K-wire at L5 up into L4. He's pulling on the K-wire. It tends to want to go forward a little bit. Now you can see the docking process.
01:03:15
JONATHAN HYDE, MD: X-ray. X-ray. Let's get an AP shot.

01:03:20
WILLIAM TOBLER, MD: As the threads are coming closer and beginning to line up with the S1 component. We're getting an AP -- AP shot here.
01:03:35
JONATHAN HYDE, MD: Okay. And you can even see on that shot, you can see the tapers kind of falling in there.
01:03:40
WILLIAM TOBLER, MD: Yeah.
01:03:41
JONATHAN HYDE, MD: So let's just bring it a little bit more. The thing is, should I take out the guide wire yet? Oh, man. X-ray. Okay, let's go to lateral.
01:03:54
WILLIAM TOBLER, MD: It's an extremely tight press fit.
01:03:55
JONATHAN HYDE, MD: This is a workout, man.
WILLIAM TOBLER, MD: Yep. Extremely tight.
01:04:02
JONATHAN HYDE, MD: Okay. X-ray.
01:04:08
WILLIAM TOBLER, MD: Continues to advance, and he'll advance that until it's all the way in. Now, once this connects, once the screw threads connect, any further insertion will actually distract over, open L5-S1. But he doesn't really need any distraction.
01:04:25
JONATHAN HYDE, MD: I'm going to just do a little bit here. So let me do one half-turn. X-ray. What? One more?
01:04:40
WILLIAM TOBLER, MD: Making his final attempt --
JONATHAN HYDE, MD: Oh, yeah. X-ray. I'm done.
01:04:45
WILLIAM TOBLER, MD: Finished. And you can see -- you can see the section, the waistbands of the A/B and the B/C components are correctly across the center of the disc space. So what he's looking now is he's looking at his final alignment. You see a nicely restored lordosis and disc height. Well, yeah, it's 1:36, so we certainly take more time with a two-level than a one-level, but you know, the important thing with respect to performing this operation is to take every step very slowly, deliberately, and you certainly don't have any need to race against the clock. But the time -- time of operation -- time of operation for this procedure is really more or less very similar to the time that it takes you to do an open ALIF. About an hour generally.
01:06:02
JONATHAN HYDE, MD: Give me a forcep, please.
01:06:03
WILLIAM TOBLER, MD: The interbody portion only. Well, we can go back -- we can go back to the PowerPoint presentation. Now, what we have here is we have that same patient. I wanted to show a facet screw fusion. The two -- two pictures below show the placement of the facet screws immediately post-op, and you can see how nicely fused the facets are. So if we go back to the -- let's go back to the program here and look at the lateral fluoro shot. You can see an excellent trajectory in the lateral view. The goal of the -- now we're going to go back to an AP.
01:07:04
JONATHAN HYDE, MD: That looks great, Larry.
WILLIAM TOBLER, MD: Very good alignment on the AP here.
01:07:06

JONATHAN HYDE, MD: Perfect. Okay, Larry, you can pull out for now. Okay, I'm going to need a Weitlaner and some zero Vicryl so I can start closing this guy.
01:07:12
WILLIAM TOBLER, MD: So we're ready to close. The operation is finished. Simply remove -- remove the outer cannula -- remove the outer cannula, the exchange cannula and suture the sub-Q, a few sub-Qs, and then a running -- a running sub-Q for the skin. And we usually use -- usually use Dermabond. But we're finished with the AxiaLIF, the two-level AxiaLIF is completed. Yes.
01:07:46
JONATHAN HYDE, MD: Yes, I am.
01:07:47
WILLIAM TOBLER, MD: We're going to do posterior fixation with facet screws, but the AxiaLIF portion of the procedure is completed successfully. We go back to the PowerPoint presentation while he's closing. I don't know if anybody's really interested in watching him close the sub-Q here. Here is a case of pseudarthrosis. Now, I have to tell you that at least I'm not going to classify somebody as a pseudarthrosis until I give them a one-year follow-up. This patient -- this patient's clinical outcome was no improvement. He had persistent pain. This is -- this is the best example that I have of a pseudarthrosis. You see -- in the upper left-hand corner, you see the halo around the L5 and both the sacral portion of the TranS1 screw. And then the axial views, you see halos around the S1 screws. So that in combination with the failure to improve is certainly indicative of pseudarthrosis. Now, there are patients that we've seen with halos around the L5 portion of the screw but they go on to fuse, so some of this is physiologic. And patients with excellent clinical improvement in their pain and ODI profiles and documented bridging fusing bone across the L5-S1 disc space. I do have a picture here of a two-year follow-up sequence. On the left, six months. You see bridging bone on the right. And on the two-year, more visible bridging bone. Here's another set of two patients with two-year follow-ups. The two-year follow-up scan looks better in every case. The bottom set of figures is a patient with a tall disc. She has a mobile spondylolisthesis. And on the one-year image in the middle, I think you can see bridging bone. And on the right side, you can see more proliferation, greater proliferation of bridging bone. Now, this -- this PowerPoint presentation here, you see an obese patient. And I just point out on the middle slide that the ALIF approach, you'd be up to your elbows in trying to get exposure to the ALIF portion of this procedure. Paradoxically, the heavier the patient is actually, the easier the TranS1 procedure is because the -- the presacral fat space is bigger. Generally speaking, it's bigger in a more obese patient. However, the distance -- the distance measurement from the L5-S1 disc to the tip of the coccyx does not change with the increasing girth of the patient. Are we still on the PowerPoint? Okay. So here is an AxiaLIF solution for a patient with a pseudarthrosis. This patient had an allograft interbody with an ALIF approach, and he also developed a fusion, and the posterior hardware was removed. So he had a pseudarthrosed segment at L5-S1, and I think you can see the pseudarthrosis here. So we took a new approach access so we didn't have to operate -- re-operate through a scarred-up ALIF approach and placed the TranS1 screw here, packed the disc space, and here you see his one-year follow-up CT. Three sequential parasagittal images showing solid -- solid fusion of the pre-operative pseudarthrosis. The next case that you see here is kind of an interesting solution in my opinion because this patient had undergone an ALIF at L4/5 with a femoral ring allograft and posterior fixation with pedicle screws and he had a solid arthrodesis and eventual failure of his L5-S1 segment. So the typical way that we would approach this prior to the AxiaLIF technique would be to come back through an ALIF approach, do the L5-S1 exposure interbody fusion, and then open him up, open the patient up

posteriorly, remove four pedicle screws, and replace them posteriorly. So we elected not to do that, and in an operation that essentially was done with the TranS1 approach and a posterior fixation with facet screws. We did the operation as if that construct at the L4/5 level was not even there. It did not interfere with the approach. And so I think that what this case illustrates is the opportunity to offer the patient something better, at least in terms of my surgical capabilities. So we have -- we've carefully analyzed -- we've carefully analyzed our first 50 patients in follow-up, and we've -- using -- using an independent neuroradiologist and looking at our results in our first 50 patients that we had for one-year follow-up, 44% of those patients had fusion by our criteria. Five of those patients, or 10%, were in the developing bone category. And one patient, or 2%, had a definite pseudarthrosis. Now, in that developing bone category, there were two patients whose pain profiles did not improve. They possibly may be going on to develop a pseudarthrosis. But even as of this date, I don't have any definite documentation that they're pseudarthrosis. So conservatively, our fusion rate was 88% at one year using our criteria. Now we -- we also did flexion/extension films, and lack of motion on flexion/extension films is sometimes used as the sole criteria for determining fusion in some patients. And interestingly, all of our patients, 100% of our patients at 50 -- at one year had no motion on flexion/extension. So there are different criteria used, and flexion/extension --

01:15:13

JONATHAN HYDE, MD: Bill, we're going to start getting ready to start some of the facet screws.

01:15:15

WILLIAM TOBLER, MD: We're going to go back to the program here. So the incision's closed, and what we're doing here is determining our entry point for percutaneous facet screws. And the facet screws will be placed at both L4/5 and L5-S1 through one incision. One incision roughly at the level -- roughly at the level of L4/5. What you see here is Dr. Hyde is -- actually has a thin cannulated guide probe, and he's coming from a midline approach obliquely across the facet. Now, the facet really is very easy to identify radiographically. And it actually is a -- it's almost round, like the face of a clock. So what he's -- what he's looking at here is he's looking at the facet on the right at L5-S1, and you can see the round nature of the facet. He's actually going to enter at about 11 o'clock on the face of the clock. And he's coming in the coronal plane at almost a 45-degree angle, across the facet, and then he's actually going to aim for the top of the pedicle in the lateral view. So he'll tap -- he'll tap the cannula into the outer cortex. So you see, it almost looks like an S1 pedicle screw trajectory in the lateral view.

01:17:02

JONATHAN HYDE, MD: X-ray. The key is being divergent. Give me an AP shot.

01:17:09

WILLIAM TOBLER, MD: So what he'll do now is he'll remove the -- he'll remove the central cannula and then take a very thin K-wire. See, you can see the facet very well. So he's entering at about 11 o'clock on the face of the clock.

01:17:28

JONATHAN HYDE, MD: X-ray. Okay, let's go lateral. Okay, K-wire.

01:17:44

WILLIAM TOBLER, MD: So he has a very thin K-wire with a sharp, beveled edge. And he's simply going to advance that with a trauma drill.

01:17:55

JONATHAN HYDE, MD: Get the K-wire driver, please.

01:17:59

WILLIAM TOBLER, MD: Just going to drive that through the facet about 25 millimeters. So he's driving the K-wire. It's a little bit awkward. The K-wire's very thin and the drill's pretty heavy.
01:18:23
JONATHAN HYDE, MD: I usually do this on the other side, by the way.
01:18:32
WILLIAM TOBLER, MD: This is sort of like rubbing your stomach and patting the top of your head at the same time.
01:18:40
JONATHAN HYDE, MD: This is not my usual operating room, so I'm usually standing on the other side with the C-arm in the opposite direction. X-ray. Larry? That's what I like to see. I'm going into the pedicle, which is great.
01:18:53
WILLIAM TOBLER, MD: Coming live from O.R. number one. Number one was your usual operating room.
01:18:59
JONATHAN HYDE, MD: This room? Nah.
01:19:03
WILLIAM TOBLER, MD: Okay, so he's moving -- yeah, it's a little easier to stand at the top of the table. So you can see on the AP shot, you can see that the wire's advanced across the facet -- advance it across the cleft of the facet. And you know, we're basically kind of repeating the AxiaLIF trajectory, so we're going to use the K-wire and drill and tap over the K-wire through a -- through a small tube.
01:19:35
JONATHAN HYDE, MD: Now I'm going to start working on the other side. X-ray.
01:19:41
WILLIAM TOBLER, MD: So now he's developing his -- he's advancing his guide probe into the one o'clock portion of the -- the one o'clock portion of the clock on the left -- left L5-S1 facet. So again, he's lining up the trajectory -- lining up the trajectory kind of like an S1 pedicle screw. And you can see the round hump of the facet on the lateral view so you move beyond the top part of the rounded portion of the facet so that you're not -- not skiving off the inferior margin of the L5 facet.
01:20:31
JONATHAN HYDE, MD: Okay, x-ray.
01:20:33
WILLIAM TOBLER, MD: Going back to an AP.
01:20:34
JONATHAN HYDE, MD: X-ray. I'm going to take that. That's okay.
01:20:38
WILLIAM TOBLER, MD: Again, he's at about a 45-degree angle, about a 30-degree angle -- 30 to 45-degree angle on the coronal view. And about a 45-degree on the -- in the lateral.
01:20:53
JONATHAN HYDE, MD: Larry, can you tilt it over to me a little bit more? I want to see something for a second. Tilt it way over here. X-ray.
01:20:58
WILLIAM TOBLER, MD: So what he's doing is he's actually -- yeah.
01:21:01
JONATHAN HYDE, MD: I see the joint. I'm okay.
01:21:03
WILLIAM TOBLER, MD: What he's actually done is an oblique view, and you can see obliquely right into the facet cleft.
01:21:08

JONATHAN HYDE, MD: I'm a little bit inferior in the joint, but I am in the joint, so I know I'm okay. Let's go to the lateral, Larry.
01:21:15
WILLIAM TOBLER, MD: This -- this -- this technique is fairly unfamiliar, especially to neurosurgeons. Most orthopedists -- but not all -- most orthopedists have had some familiarity with facet screws, some neurosurgeons. But I think mostly the neurosurgeons that I encounter have not had any experience with facet screws, so you have to look at the facets in a way that you haven't been accustomed to. But it's really very easy anatomy. So he's advanced his wire, going to check it on the AP.
01:22:02
JONATHAN HYDE, MD: Shoot. That's okay. That's beautiful. I'll take that.
01:22:08
WILLIAM TOBLER, MD: So he's got his wires at L5-S1.
01:22:14
JONATHAN HYDE, MD: Okay, let's dilate. I lost my earphone, by the way.
01:22:18
WILLIAM TOBLER, MD: Now what he's doing, he's got -- he's got like a 10-millimeter dilator with an outer cannula, except this is about 5. And so he's going to remove -- going to remove the inner stylet so he's left with the wire and a small dilator tube. Then he has a drill, going to use the trauma drill again to drill a channel through a cannulated drill bit through the facet. And that's going to go 25 millimet-- you're going to use a 25 or a 30?
01:23:03
JONATHAN HYDE, MD: Twenty-five. It's pretty shallow.
01:23:05
WILLIAM TOBLER, MD: Yeah. There's two different size -- two different length facet screws, 25 and 30 millimeters. And this L-- this facet screw has a diameter of 5 millimeters. So could we take a look at the screw before you put it -- get a close-up view of the screw? It's a cannulated titanium screw, 5 millimeters in diameter, places it over the little K-wire.
01:23:41
JONATHAN HYDE, MD: X-ray.
01:23:42
WILLIAM TOBLER, MD: And then threads it down the channel that's been drilled.
01:23:47
JONATHAN HYDE, MD: X-ray. X-ray.
001:23:53
WILLIAM TOBLER, MD: Generally goes in pretty easy, and you can see the tip of the screw. He's down almost all the way. And you can feel -- you feel the resistance, it's very tactile again.
01:24:01
JONATHAN HYDE, MD: You only need two finger-- it's two-finger tight.
01:24:05
WILLIAM TOBLER, MD: Right, just -- just very slight change in resistance as it engages the outer cortex of the surface of the facet. So he's removed the screw and the K-wire, putting the dilator down on the right side, simply going to repeat -- going to repeat the same maneuver. Move the cannula. He's going to drill with a cannulated drill bit and then advance -- advance the drill. So he's advancing -- advancing the final S1 screw -- L5-S1 facet screw.
01:25:05
JONATHAN HYDE, MD: X-ray. X-ray. X-ray.
01:25:16
WILLIAM TOBLER, MD: You can see the screw head going down on the lateral fluoro.

01:25:24
JONATHAN HYDE, MD: Let's get an AP shot, Larry.
01:25:25
WILLIAM TOBLER, MD: Two-finger tight. Going to get an AP shot. And so now you see the -- you see the L5-S1 facet construct with the two-level TranS1.
01:25:44
JONATHAN HYDE, MD: Larry, I want you to go back to a lateral now. We're only going to do 25s.
01:25:50
WILLIAM TOBLER, MD: Now we're going to go up to the L4/5 level. Can we go to the PowerPoint presentation? Because I want to show you this -- show you this picture that shows the sequence of dilation, advancing of the facet screw over K-wire, and most importantly, what you see in this operation, the two-level L4/5, L5-S1 anterior posterior fusion is the incisions. Two small incisions, the paracoccygeal incision for the two-level AxiaLIF is about 20 millimeters. And the incision for the facet screws is about 8-10 millimeters. And essentially zero muscle disruption with the anterior approach and certainly the trajectory for the AxiaLIF does transgress, but I think minimally, the paraspinous muscles. Now if we go back to the -- if we go back to the live fluoro here, Dr. Hyde is now advancing -- advancing his -- advancing the guide probe both on the AP and the lateral fluoro shot. Again, in the lateral view, you can see the facet very easily, and he's just angling a little bit downward, but it almost looks like the pedicle screw placement on the lateral, tapping the -- tapping the guide probe through the cortex. And then he's going to do the same -- repeat the same maneuver. Can we go back to the PowerPoint presentation? So what you see here -- what you see here is the desired appearance of the facet screws in their final position in the sagittal and axial views on the CT at this L5-S1 360 construct. You also see the bone-graft material circumferentially around the TranS1 screw in the L5-S1 disc space. But the technique of placing the facet screws is really very straightforward and you actually have a fairly big target for the facet screws, so the learning curve is not very difficult for the facet-screw placement. Can we go back to the fluoro?
01:28:53
JONATHAN HYDE, MD: So I'm just making sure I'm getting the appropriate divergence of the facet screw. X-ray. That's looking pretty good. Let's go back.
01:29:03
WILLIAM TOBLER, MD: Again, on the right side, you like to enter about 11 o'clock on a clock face. He's just advancing --advancing his K-wire with the drill.
01:29:15
JONATHAN HYDE, MD: Perfect, going right to the top of the pedicle. Safe spot. Let's do the other side.
01:29:22
WILLIAM TOBLER, MD: Now he's going to go to the opposite side, to the left side.
01:29:31
JONATHAN HYDE, MD: X-ray.
01:29:34
WILLIAM TOBLER, MD: We have done this procedure, the TranS1 360 at L5-S1, in the outpatient setting, and I don't anticipate that the patient's perception would be terribly different for the two-level -- for the two-level procedure. I anticipate that two-level AxiaLIF can probably be done in the outpatient setting as well.
01:30:11
JONATHAN HYDE, MD: Shoot, Larry. You've got a little rotation, you're not pure AP. Right there, x-ray.
01:30:16

WILLIAM TOBLER, MD: Right down to facet -- a pedicle view.
01:30:23
JONATHAN HYDE, MD: X-ray. X-ray. That's going to be good. Let's go to the lateral.
01:30:30
WILLIAM TOBLER, MD: Looking for the final trajectory for the left-sided facet screw.
01:30:34
JONATHAN HYDE, MD: I don't know, Bill, it's almost an hour and a half. We're almost done with the whole surgery.
01:30:40
WILLIAM TOBLER, MD: About an hour and a half since we made the incision. What you didn't see -- what you didn't see, though, on the live video was the positioning process of the patient, and that takes a little bit of time and preparation and education of the O.R. staff.
01:31:03
JONATHAN HYDE, MD: I mean, here it's almost --
01:31:04
WILLIAM TOBLER, MD: Patient's positioned prone. You want to make sure that you have good lordosis. And it's important that the patient's legs be spread apart, widely spread apart, because during the initial approach, we're dropping the guide pin sort of between the legs. So the legs need to be spread apart. I always put a Foley catheter into the rectum. And it's personal preference, but I like to inject air into the rectum if I can't see the rectum outline before I start the procedure. We usually put three-inch tape with some adherent spray and spread the buttocks apart, clean with alcohol sponge very carefully, and then drape a 10/10 drape right across the -- horizontally across the top of the rectum.
01:32:15
JONATHAN HYDE, MD: Same screw, 25.
01:32:16
WILLIAM TOBLER, MD: I think we're pretty good right now. Do we have some questions?
01:32:24
JONATHAN HYDE, MD: X-ray. See, Bill, I don't have my headphone, so I can't hear anything that they're saying, okay?
01:32:29
WILLIAM TOBLER, MD: Okay.
01:32:36
JONATHAN HYDE, MD: If there's any questions, just tell me.
01:32:37
WILLIAM TOBLER, MD: Yeah, the question is: is it possible to do this in a patient with osteoporosis and more often, osteopenia? I certainly -- certainly in a patient with significant osteopenia or osteoporosis, I would probably use pedicle screw fixation.
01:32:56
JONATHAN HYDE, MD: I agree.
WILLIAM TOBLER, MD: I would definitely not do a stand-alone off-label use of the AxiaLIF procedure without posterior stabilization and with the strength of the pedicle screw fixation.
01:33:15
JONATHAN HYDE, MD: K-wire driver.
01:33:22
WILLIAM TOBLER, MD: You know, that depends on an off -- that question was: do I -- do you think that I will do more L5-S1 fusions or more two-level AxiaLIF fusions in the next year? I will certainly do more L4/5 and 5-1 AxiaLIF procedures in patients who are appropriately evaluated for the need for fusion surgery and have the

appropriate trajectory and sacral anatomy for a TranS1 approach. With regard to more or less L5-S1s, I mean, it depends on an awful number of different factors. I think that if patients have an increased awareness of the benefits of this procedure compared to some of the other standard, more commonly used procedures, there might be increasing patients asking for this procedure. I think that that certainly can change as the awareness increases. Do you have another question? Okay. Dr. Hyde's advancing the screw on the right side. I think he's finished. And then he just has the last screw to remove. One more screw.
01:35:10
JONATHAN HYDE, MD: What do you mean? What are you talking about?
01:35:13
WILLIAM TOBLER, MD: Oh, my God, he's got both of them in. Jeez, I'm not paying attention.
01:35:18
JONATHAN HYDE, MD: Let's get an AP shot.
01:35:19
WILLIAM TOBLER, MD: Can we get an AP shot? Yes.
01:35:26
JONATHAN HYDE, MD: Could've put the screw a little bit higher in 5-1, but it's okay. It's in, we checked it.
01:35:32
WILLIAM TOBLER, MD: Dr. Hyde, we're going to look at an AP. Do you have a final comment? We're going to finish the broadcast here. We're just about finished.
01:35:43
JONATHAN HYDE, MD: The comment that I have is actually the case went actually better than I thought. I think that this is a really nice, novel way of doing 4/5 and 5-1. The time, something like this, I would've done an anterior procedure previous or have done maybe a TLIF previous at 4/5 and 5-1, maybe an XLIF at 4/5, but I would've had to turn the patient in some of those anterior procedures and then gone back. And this has actually taken just a little bit over an hour and a half. My PA will finish up the skin and it's nice. We went through basically aneural planes for the entire procedure, and I think this patient, after we're done, I would expect in about two or three hours, be up walking around and probably go home in the morning. I think, as you were saying before, I wouldn't be surprised eventually if something like this, such as the one-level, is being done in outpatient settings. I think this would definitely lend to that. It's just, again, one incision for the facet screws, one incision for the TranS1 approach, so it's actually a very -- looks like it'll be a very nice, well-tolerated ambulatory procedure as well as an inpatient procedure.
01:36:54
WILLIAM TOBLER, MD: Very good. Thank you.
01:36:55
JONATHAN HYDE, MD: Thank you, everybody.
01:36:56
WILLIAM TOBLER, MD: This -- this concludes our live broadcast of a two-level AxiaLIF 360 fusion. I would like to take this opportunity to thank the staff of Mt. Sinai Hospital, everybody who's in this room who tolerated our intrusion during this period of time. I appreciate their cooperation and professionalism. I thank the hospital. Thank you very much.
01:37:27
JONATHAN HYDE, MD: Thank you, everybody.
01:37:41
[end of webcast]