LEGION™ Total Knee System with VISIONAIRE™ Patient Matched Instrumentation

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Welcome, everyone. I’m Dr. Steven Haas from the Hospital for Special Surgery in New York City. And I’m here tonight with Dr. Ken Cherry. We are coming to you live from Mount Nittany Medical Center in State College, Pennsylvania. That’s the home of the Penn State Nittany Lions. And before I begin, I want to let Dr. Cherry and the Mount Nittany Medical Center - I want to congratulate them on their award by Health Grades as the number one hospital for joint replacement in all of Pennsylvania. I congratulate them. Tonight, Dr. Cherry will be performing a Legion total knee replacement using the VISIONAIRE Patient Matched Instruments.

And before I begin, I’d like to do a brief presentation on the Legion and VISIONAIRE technology. The Legion total knee replacement system is a comprehensive system including primary knees, both cruciate retaining and posterior stabilized and revision, all using the same instrumentation and the same system of components. Essentially with the primary knee, you can go with PS or CR and go all the way from the high demand patient with a high flex posterior stabilized, or cruciate retaining, all the way to the complex patient with a constrained knee. In addition, there are highly crosslinked polyethylene, along with Oxinium for that high demand patient who you really want to get longevity out of the implant. The Legion system additionally includes multiple different patella options, augments for the complex revision, stems and offset couplers for the complex and deformed anatomy.

The instrumentation you’re going to see tonight and some of the things I think are very unique. The thing that I think is terrific is, first of all, as far as the sizing and rotation guides, you can use the AP axis, the epicondylar access, or posterior condylar axis to determine your rotation. And then uniquely, you can prepare the posterior stabilized box directly through the trial, saving time and providing increased accuracy. All of the revision instruments are intramedullary based, the low profile instruments, so that they don't impinge on the soft tissue.

What you’re going to be seeing tonight is the VISIONAIRE instruments. The VISIONAIRE are single-use, patient-matched instruments that are designed based on MRI and long-standing x-rays, so each instrument is designed specifically for that patient, essentially a from of preoperative navigation.

When you do the preoperative navigation, or VISIONAIRE instruments, you get essentially a readout of the patient's anatomy, along with all the bony resections. Dr. Cherry is going to go over this a little bit more in detail on the patient we're going to do tonight. So I'll pass this to him when the time comes.

Once the MRI and long x-ray are done, this information is sent off to Smith & Nephew. A model is then made on the computer of the patient’s femur and tibia. This slide shows the femoral anatomy. Once this is done, the operation is planned, and essentially the bone cuts are made and the implant is placed essentially during a virtual operation on the computer. This is done according to the preferences of the surgeon and left to review and approval by the individual surgeon. This is a picture or diagram of what it looks like on the femur. And this is the same model for the tibia, essentially the computer model cuts and how the implants will be seated once they’re in place.
This slide shows what the instruments look like once they're placed on the bone. And all these photos are given to the surgeon prior to the surgery. Any changes the surgeon wishes to make can be done. As I noted, the plan for VISIONAIRE is based on a long-standing x-ray for the knee. This is a comfortable way, I think a way that most surgeons have been used to aligning the knees. The surgeon can choose to align it off of a mechanical axis, which is the most common preference for most surgeons. However if the surgeon wants to vary that and leave the knee in a degree or two of varus or has some other anatomic variant that the surgeon wants to modify the plan, the he can do that with the engineers preoperatively.

I want to talk a little bit about VERILAST technology. VERILAST technology is really exciting technology, especially in the age of when we're doing knee replacements in younger and younger patients. I know my patients more often now, many of them are in their 50's, some of them in their 40's. And this is a trend seen around the country and in fact even internationally. What this slide shows is with crosslink polyethylene, you can see that there is decreased wear when tested, the higher the radiation does. However, even at 9 megarads, which is a very high dose, you can see the rate of wear here increases dramatically as they all do when you use a rough-in component. In other words, real components get roughened and scratched in the patient. And what happens is this dramatically accelerates the wear, especially with crosslink polyethylenes. So, VERILAST technology combines the smoothness and scratch-resistant surfaces of Oxinium with crosslink polyethylene. So, in fact, the wear rates with this at a lower dose of radiation, a lower megarad dosage, can achieve wear rates both in the pristine state and then note in the rough-in state the Oxinium surfaces done become rough-in, therefore you don't get that marked acceleration of wear. And so you continue to get the low wear rates and the benefit of the crosslink polyethylene.

As many of you may know, the VERILAST technology has been approved by the FDA so that it has the ability to last for 30 years, which is, from a wear standpoint, a quite dramatic improvement over what has previously exited. And I want to share a little bit about how that came about. This is essentially what the testing was done according to the FDA protocols. And if you look at the wear rates, even at three years of simulated wear, the test standard three years, of chrome cobalt on essentially conventionally polyethylene, and look at this compared to the VERILAST, which was tested at 30 years, 45 million cycles, 30 years of simulated use. You can see that the wear rates are 81 percent lower. So you can see there's really a magnitude. So, at 30 years, 80 percent less wear than the conventional polyethylene on chrome cobalt at only three years. So there's really a quite dramatic reduction in wear. And this what the FDA used to give Smith & Nephew the approval.

I've completed that presentation. I'd like to move on to Dr. Cherry, who will be going over the details of this specific case tonight. Thank you. Dr. Cherry?

Thank you, Steve. Welcome again to State College. As Dr. Haas has pointed out, we are going to use the VERILAST technology today along with the VISIONAIRE technology in the Legion knee replacement. We have chosen a particularly challenging case, I think so show you how versatile and how accurate this system is. This particular patient we are dealing with tonight has rather large size bone and has very significant soft tissue challenges in that he has a 20 degree flexion contracture and marked varus deformity of they knee. This is a typical preoperative setup from VISIONAIRE. We have our preoperative plan, as we call it, with a great deal of information provided to us. This tells us the alignment deformity, the true mechanical alignment, the sizing, and allows to plan our bony resections. In this case, working with the engineer, you can see that I've changed the distal femoral resection from the typical 9 mm. to 11 mm. because I know that the patient has a significant preoperative flexion contracture. So I can build in a little bit of extra bone resection into my block and plan that accordingly ahead of time.

I have my resections marked out up here on our plain x-rays. This tells me the bony resections that I'll be dealing with and allows me to plan my soft tissue releases a little more accurately. In
this case I know I have 7 mm. less medical bone resected that I have to account for in our soft tissue release. So, I’m combining that with his preoperative examination. I will have an idea about what I need to take down preoperatively or interopertatively to balance his ligaments instead of going in blindly. Again, this is the plan. This is how we expect the components to fit. And so now I’m going to move over and we’ll get started.

What I’d like to do while Dr. Cherry is preparing for the case is to show you the blocks themselves, the instruments. This is a replica of the instruments that Dr. Cherry is going to be using today. On the instrument is the patient’s name along with the size of the implant so there’s no confusion about what block you’re going to be using. Additionally, what this guide will do – this is the femoral guide – this will set the distal resection, the varus/valgus alignment and will set the rotation. These two holes line up with the holes that’s at the AP position and the rotation and I would actually argue far better rotation alignment than we can determine by looking at this interopertatively since it’s based on an MRI scan.

Now, a few details of these guides. These pins on the top line up with the standard distal femoral cutting blocks. So, should you decide that you need additional bone resection, one can use the guide, the standard guide, if needed. In most cases, you can plan ahead, as Dr. Cherry has done, to take additional resections. But if you hadn’t you can still go back and take further bone.

I just want to show how this fits. This is a model that was made of this patient based on the MRI. And you’ll see that placing this is incredibly easy. They are stable. It isn’t like you have to search for the right spot. It’s a complex geometry, and so it only fits really in one plane. Similarly on the tibia, a few features on the tibial guide, in a similar fashion, these two are going to reference the medial and lateral tibial plateau. The key thing that was done in VISIONAIRE to provide excellent stability of the guide was the anterior surface of the tibia is molded into the front of the guide so that when it sits on the bone, again similar to the femur, is only goes in one rotational location. So again, you don’t have to decide, moving it back and forth. This guide will fit only in one direction and there’s reference lines to line up with the tibial tubercle, the rotation of the tibia can be set. And again, like the femur, these two pins line up with the standard tibial cutting block so that if you need to go back and cut additional bone, you can use the existing pins.

I’d like to go back to Dr. Cherry, who’s going to show us the instrument setup for the VISIONAIRE Legion knee. Dr. Cherry?

Okay, before we start, I just want to show you one of the other big advantages of this system is you’re seeing a shot of our back table. And really, this is all the instruments that we need to prepare for this case. Even though this is a complex deformity, we know the patient’s size preoperatively so we have the appropriate size femoral and tibial components, an assortment of tibial implants and our patella instruments. As you can see, this is a very simple and easy back table setup which shortens the turnover time and lessens, I believe, the stress on all the hospital staff in setting up one of these cases.

So with that, I think we’re ready to start. I just want to show you again. This is our patient in fairly significant flexion contracture, fairly large size bone and a fairly rigid deformity. So, we’ve kind of marked out our landmarks, the tibial tubercle, the patella, and we’ll go ahead and get started.

You know people often talk about the costs of procedures. And if you look at that efficiency that can be created by these instruments, the fact that setting up these instruments and setting up the case with fewer instruments saves time in turnover. It additionally saves the- if you’re doing multiple cases, preparing instruments for each case. So knowing the size of the implant, knowing the alignment of the implant, not having to have additional instruments saves setup, saves surgical time and saves turnover time. So, I think that there are many, many reasons why this can create efficiency, which I think is really the future of medicine is going to be how we can do things not only better but better and more efficient.
Typically, when we do this, knowing the size helps me plan the approach. On a more normal size, I would be doing a mid-vastus approach. With a really large size femur like this and a fairly rigid deformity, we’ll do the more standard medium parapatellar approach. But again, the mid-vastus is a nice approach. And in most of my patients that are normal size, it’s my approach of preference. I just want to make sure that I can get the patella out of the way. Mayo scissors.

Yeah, when this patient’s size to a size 8, which is the second-largest size that exists for the implant, so quite large patient. When these patients come in and say, “Can I have an MIS?” I say, “Whatever size you would give you that is an MIS.”

Yeah, that’s a great point. Yeah, the incision usually is a good bit smaller but you need obviously to get the components in and see. And in this case, we have to make the incision a little bit bigger because we’re dealing with very large size components. We’re making a little window here on the anterior femur. This is to allow the cutting block, the patients match block that Dr. Haas demonstrated, to sit nicely against the bone. We don’t take a great deal of senobial tissue out, just enough to allow that block to sit down. Right now, we’re just kind of preparing the soft tissues for the surgery. I’ll show you here in a minute what we do as far as our planned soft tissue release. Kind of just getting everything exposed right now.

You know the other thing is the instruments help in balancing the knee, but you still have to do your soft tissue balancing. If there’s a varus knee you can plan for, but it doesn't negate the fact that you do ligament balancing. I think we have 30 years of experience saying good ligament balancing is crucial. And I think that doesn't change here. I do find that doing rotational balancing and flexion is a bit easier because I think my rotation is more accurate. I know sometimes I would the lateral side would be a little loose in flexion, probably because I under-rotated, whereas I find that it doesn’t happen. It’s easier to get your flexion gap balance. But I don’t want to minimize. I think soft tissue balancing is always an important element of knee replacement.

Yes, the beauty of this is that we, knowing the bony resection levels and knowing what I call the pseudo-laxity of the tissues, you can plan your soft tissue releases a little more, I think, accurately. We know that I have 7 mm. – pickups – 7 mm. of bone to make up medially here. And so, I'm going to do a little more exposure here on the medial side than I normally would. When that number is down around 2 or 3, which it typically is, then I would not have to expose nearly as much of the medial side of the knee to balance the ligaments. I’m still not going to do a big release. I’m not going to strip this whole posterior medial corner, just going to do enough right now that I can see. If I have to do a little more later, I can, but that’s pretty much going to be our exposure for that.

So, you can tell Pennsylvania surgeons, as opposed to the New York surgeons, we get scared when we see these big guys. The Pennsylvania, they’re tougher.

So, we're just amputating the anterior horn of the medial meniscus. This allows me to kind of see the joint line a little bit better. Again I’ve taken down just a little bit of the medial side of the knee, but not enough- you know I've not really subluxated that posterior medial corner. I just want to get enough that I can see the balance here, and I’m trying to be very careful with the soft tissues and not doing a big soft tissue release.

Now, we have a fairly decent view of the femur. We're just going to take out our cruciate ligaments, and then we'll be ready to actually- we have the exposure we need, we're ready to start. And we'll do our femur first. With this technique, I'm just going to make a little- so we have a good exposure of the femur.

We're now ready to apply the block. Again, one of the beauties of the VISIONAIRE technology is we're not drilling a hole in the femur. We're not violating the intramedullary canal, creating additional blood loss. You can get a look. The block is now placed on the patient. It’s a nice –
as Dr. Haas said – it's really not a struggle to get this to fit. You can see that we have a very snug fit, but it's rock solid and we pin it in place. We use four pins. The technique calls to pin the distal holes first. This sets the rotation of the femoral component. And then we pin our two anterior femoral pins. These corresponds to the femoral cutting blocks. Now, we've built an additional 2 mm. into this. All right, so we'll do our femoral distal resection.

Ken, that was very nicely coordinated there to get that pin out. Is that the way you usually do it as you're cutting, remove it?

Yes. I like to leave the pins in to help hold the block. And Jennifer removes them as we approach each side. Now, what we can do is slide this off and check our distal femoral resection. In this case, we're into the sulcus just about 1 mm. or so. We have some pretty big osteophytes here. Can you put that saw back just to finish this medial femoral? There's a really large osteophyte here. To me, this looks like a really good resection level.

I also find it very nice that you have a check when you're doing the operation. Because you can measure those bone resections.

Yes, you can, yes.

And if you want to, you can confirm that you're proceeding according to your pre-op plan.

You also – can I have the distal femoral cutting block there – if you weren't satisfied, again, you can take this block. It first right over the pins, and you can take an additional 2 mm. of bone just like that. And so, you can cut right through the block. In this case, I feel that we have enough bone that we'll be okay. We're into the sulcus and my extension gap looks pretty close.

And sometimes what I do is I mark those holes so that if I need to come back and do distal resection-

Yeah, that's a good point.

Put it back in those holes.

These two holes, you can find fairly easily to mark them with a marking pen.

Ken, I have a question. How long do you say it is to review the pre-op plan?

I would say, on average, the pre-op plan takes me about three to four minutes, maybe three minutes. I usually have my preoperative digital x-ray, the plan and my office note telling me what the deformity is, if there's any soft tissue contractures and what the range of motion is. And then I use that, combined with my plan.

I also find it's easier, when you first start you might spend a little time with the engineer to get your preferences. So you want to say that what do you do if you're in between sizes. The default [inaudible] because for some of the cases, it barely takes me a minute to do a pre-op plan because they know my defaults. For a complicated case more like this one, it might take, you know three to five minutes. But for a routine case, I just have to look at it and say it's routine, and don't need to go anything, just look at it.

This is a really large, as you can see, a large individual as far as bone size.

I have a question that's asking- a young person actually is asking. They're very interested to know, as a young person - young is always a relative term as I get older. But I'm assuming maybe younger than me – the person wants to know what's the youngest person that I've operated on using the VERILAST technology. And I think that since the VERILAST technology, I
know several 39-year-olds and a 35-year-old. I think that’s the youngest I’ve done. I’ve done younger patients that are in the past that were rheumatoid. But since the VERILAST technology has become available, I think the youngest has been in their 30’s.

One of the things you may have seen, we don’t- the VISIONAIRE block allows me to set this component so accurately that we don’t spend a lot of time exposing this anterior femur and worrying about notching. As you’ll see here in a second, the cut is just flush and perfect every time with the anterior femur. We’ve created our mobile window here, so we’ve kind of brought the knee into extension to deal with the anterior parts first. But you can see the run out is excellent.

It’s true. I have notched one of these.

I’ve not seen any either.

It’s not a worry.

You can leave that out. Take the buckbill [sp] for a second.

Additionally, a nice element I find is it’s much easier to do the tibia, especially if you’re doing an MIS, or a big piercing surgery in this case. But, once you’ve done the femur, it’s much easier to prepare the tibia. In other words, it’s oftentimes difficult to do the AP cuts of the femur because you’ve done the tibia because you can’t fit the rotation guides in place. In this setting, you can literally complete the femur, except for the PS housing, before you do the tibia. So, it makes preparing the tibia much easier as far as exposure is concerned. Do you agree with that?

I totally agree, yes. One thing you can see, we’re trying to be careful with the soft tissues. We’re only working on one side at a time. That way, we’re not stretching and tearing a lot of the tissues. So, we try to remove our condyles in situ without subluxating the tibia. I think that tears a lot of the posterior capsular tissue and creates a lot more post-operative pain. So, we’re trying not to disturb the soft tissue. And again, this technology I believe allows you to do this much more accurately and with confidence because you know what you’re dealing with.

So now we’ve got our femur pretty much prepared, and we’re going to go ahead and move over to the tibia. Once again, I don’t like to subluxate the tibia if I don’t have to. What I’m doing right now is taking out the remnant of the medial meniscus, making sure that I don’t violate the medial collateral ligament. If I have to subluxate the tibia to get to the posterior horn I will, but if can get the majority of it out without too much work, I can slide my retractor now inside the MCL. [inaudible] So, we’re removing the medial meniscus first. Again, I’m not going to do much more soft tissue work on the medial side. [inaudible] now, we’re going to go ahead and take out the remnant of the posterior cruciate.

Ken, can you comment on- I go at question about what kinds that you’re using for the procedure.

The pins I use are a fluted pin that are provided by the hospital. They’re basically just like the smooth pins provided by Smith & Nephew just with flutes on them. I know that speed pins are very popular that can hold the block as well. I’ve just found the fluted pins seem to work the best for me. And they’re what we have available. I think they’re through Striker [sp]. But they’re just what we have available at the hospital.

Yeah, I have to say I use different pins. I think pinning is one of those, is a real preference. Different surgeons like different pins. I use headed pins for the distal holes, and I use head-less non-threaded pins for the distal femur. [inaudible] but I use headed pins to make sure the block is seated. But it’s really, I think that you- there’s a lot of preference in that. Somebody asked about what are the contraindications of this procedure. And [inaudible] what are- sometimes I was unable to do it because there was so much metal around the knee that it created artifacts. So,
I've had some patients who I could not do it on because they had existing hardware that created distortion of the MRI. Ken, are there any other contraindications that you can think of?

No, I agree. I actually say I find that I think it's difficult to find a patient that I wouldn't want to do this on other than, as Dr. Haas had mentioned, some of these patients-

The reason I say that in part also is you're never wedded to what you had set up with the instruments. A good example is if it was found that you needed to downsize the implant in this case, the holes that you made essentially fit every block that you have. So, if you wanted to go downsize, you can decide whether you need it in the front or the back – usually it will be in the back – and there's a guide that shifts the holes and then you recut taking an additional whatever you want: 2, 3, 4 mm. off the back and downsize. So you're not- it doesn't lock you into one particular – to the pre-op plan if you need to change it because of soft tissue irregularities.

So now we pretty expose the tibia. We've taken down very little on the medial side, taken out our meniscae, again trying to leave the tibia as much in situ as we can. We'll now apply the tibia cutting block. I find it's helpful to come in from the top like this and secure this block. But again, as Dr. Haas had mentioned, there are very nice contours and landmarks to make sure that that block is fitted. It's very difficult, even with the tibial contours being less, to mal-rotate this. When you come in from the top, you can see that it just fits here, it fits all along the tibia. We have a reference guide being this much, which I've marked also on the screen, corresponds with the medial 1/3 of the tibial tubercle. So it tells me that I have my rotation set correctly. So I'll hold it while Jennifer pins it.

An important point also to mention is you do not remove the osteophytes before you place the block. You can move soft tissues, but the osteophytes are still in place. So those osteophytes are incorporated into the design of the block. So they actually make the geometry [inaudible] complex.

Now, as Dr. Haas has mentioned, I do use the headed pins on the tibia, so I have two short-headed pins. And I'll hold the block on the surface and then the two anterior pins are the smooth pins because, again, I can slide this off and check this. Let's just check our alignment. I'll take the alignment checker.

Yeah, that's exactly the way I do it, Ken. That looks great.

This is when you're doing these early on, this is a system you can use. If you want to check you can slide this little alignment guide in and take the drop rod.

And I think that is nice. You can check it. You can do it on the femur too, can't you?

Yes, you absolutely can. You can get a shot here and see we're right about the second metatarsal.

That looks great.

Very nice way, if you early on- we've done enough now here that we typically don't do this step. But certainly, if there's any doubt in your mind that something doesn't look right, you can have that available to you to back check your work. So the tibia is pinned. Again, we're going to go ahead and do our resection.

That's a terrific exposure in this big guy. It really looks nice.

It's nice, the lateral pin tends to pop up a lot for you do you don't have to struggle with it.

That's a nice trick. I'll have to try that, the self-removing pin.
Yeah, the lateral one will pop up. The medial ones often in the sclerotic bone is a little more difficult to take out. So this one, because that bone is pretty dense, can be a little more of a struggle. So we'll finish our tibial cut. Sometimes on these big femurs or tibias, if I can't get – let's just show them – we can slide the block on here just like the femur, yes, this is the tibial cutting block that would slide, again using the same pins. I can change my resection level very easily if I choose to. I don't worry if I can't get this posterior lateral corner on these big tibias. I'd rather just kind of crack off the tibial plateau like this. And if there's any bone left, I'll do it where I can see it under direct vision. That way I'm not taking a chance of injuring the posterior lateral structures of the knee with the saw blade back there where I really don't have good visual control.

And a good example of the pre-op plan being that you can check that, you can see how the bone had very little bone medially and about the thickness of the blade, so there's nothing left medially because it was 1 mm. thick. And you'll have more laterally. So you know that the cut looks like the pre-op plan, so you're doing it right.

That's that little bit of bone that I said I like to just finish up like that. I can lay the blade on there and just use my resected surface as my cutting guide. And I'm not cutting blindly into the back of the knee. Okay, let me just reset this. We're ready for our base plate. So now you can see we have our tibial base exposed nicely. We'll go ahead, the rotation can be set by the holes in the tibia. I prefer to just kind of set my own kind of using my own judgment of the medial 1/3 of the tibial tubercle. Sometimes they drop right in the same holes. Sometimes my choice is just a little bit different. But I find I can control the tibial rotation perhaps a little bit better, definitely the femoral rotation, one of the beauties of this system is that it sets it so well.

I would actually argue the femoral rotation on these blocks is better than navigated knees because navigated knees, you have to put the inputs in manually. So it's whatever you tell the computer to do, whereas where, again based on an MRI, the rotation alignment is really the gold standard for judging rotation.

So now we've prepared the tibia and the femur. What I like to do before we move over, I like to do the patella with the knee decompressed. But before we do that, I do a little balancing check here by removing all the instruments, and I'll use a laminas spreader in here to check my flexion gap, kind of like a crude tetsometer [sp]. But I'll put this in here and you can see very nicely that my flexion gap looks very nicely balanced right now. So, you know just with equal tension on the collateral ligaments I can see that I've got a fairly symmetrical flexion gap laterally and medially, which gives me a great deal of reassurance that even though I've taken down very little of this medial collateral ligament, my ligaments are already balanced. And I would say if we had done sort of the classing stripping, we would be dealing with a soft tissue problem right now. This also lets me just see if there's anything I haven't gotten out. There's a little big of remnant of the posterior cruciate there that I want to remove and a little bit of remnant of the medial meniscus. Again, I don't worry too much. If I can't get those early on in the case, I don't send a lot of time with that. I think it's easier to do it either now or with the knee and extension.

There was a question about any plastic debris and whether it's been tested. And the answer is, yes it has. It's essentially inert material. You don't generate that much debris by cutting tough the block. And the material has been shown to be an inert material. And when you lavage, probably it is all removed anyway. I've never seen any sizable or visible amount of debris in the surgical field. So I don't think that is much of an issue. If a surgeon is uncomfortable for whatever reason not cutting through the blocks, you don't have to cut through the blocks. One can remove the block and then place the standard distal cutting block, or tibial cutting block as Dr. Cherry showed of a recut. You could do that as your cut. Now I'm not sure that it's necessary and I don't do that. But if you're, for whatever reason uncomfortable or a particular patient you're uncomfortable on, you can do it with the standard metal cutting block.
The other thing I'll do is just reach up in here while we have the knee in the flexion gap because-and just check my posterior condyle capsule or area, just to make sure that it's free, especially in a patient like this that had a fairly significant flexion contracture. I just want to make sure that posterior capsule is free. But I feel like my ligaments are balanced very well. And my flexion gap looks good. One other point comes to mind. Dr. Haas was talking about the inertness of the plastic. The other beauty of this is that the blocks are re-sterilizable up to three times. So if you did drop in inadvertently, you haven't lost the case. You can flash these and reuse them up to three times without affecting the integrity of the block.

And there was a question about the VERILAST and comparing it to other crosslink polyethylene. And in fact that has been done. The slide I showed was the one that was by the FDA. And the FDA wished to have the comparison to conventional polyethylene. However the testing has been done to chrome/cobalt conventional- they're crossing poly and chrome cobalt. And I showed the slide before the last one actually showed some of that. But there is even more detailed analysis of that and the VERILAST has a tremendous reduction compared to the chrome cobalt on other crosslinked polyethylene. And that's even in the pristine condition. That's less. That difference becomes much greater if you looked at either retrieved components or essentially scratched components.

We're just checking our precut patellar height here. It's about 26, okay. We free-hand the patella, kind of score it around the exposed the sinovial reflection. Probably a 41, Sandra.

Ken, there was a question. What do you think your normal tourniquet time for a VISIONAIRE is?

Well components – let me finish this so it's not so noisy. Typically the components are cemented in place somewhere between 30 and 34 minutes.

Now that's about the same as our experience, which is somewhere between 30 and 35 minutes if the time when, compared to about 45. It's about 10 minutes less. I think our average time was 47, 48 and it's about 10 minutes less for VISIONAIRE.

So that's 15, so we have an 11 mm. That will give us 26. That's good. Okay, the 41 patella will work. The other advantage, as I have said at numerous meetings, is while it saves you time interoperatively, it saves turnover time tremendously. Because obviously taking down this few amount of instruments and getting the room ready for the next case and opening the next case, there's a lot less involved when you have a lot less trays.

I think this is the data that we need to generate. Ken was one of the early users of it on a routine basis. So, this is data that I think will be coming out in the next year or so, assuming that you in fact can create a- and I think that's going to be important as surgeons want to introduce these into hospitals, that hospitals see the efficiency is where it's at from their end too. If they can turn the room over, think about the time, the cost of operating room time. In the time that it takes to prepare these cases and wasted time setting up instruments that aren't needed.

Okay, now we've prepared the patella again. I like to do that while the joint is decompressed. I think that's especially valuable in a mid-vastus approach so you're not tearing the muscle. We are going to go ahead and apply our femoral component. As Dr. Haas had mentioned, one of the beauties of these systems is that you can set the femoral component now medially laterally actually looking at the implant and set your notch accordingly as opposed to a lot of the systems make you determine your notch preparation from just a block. Here I can look and see that I have nice position of the femoral component, pin it and now do my block resection based on what the actual component is going to look like on the tibia-or on the femur, I'm sorry. I'll take the reamer first.

One more, I'd like to comment a little bit about the materials for the blocks. They're made of a nylon material called nylon 12. And it's been shown – there's even testing about its biocompatibility. so again, the idea that if you get to breed, there's going to be any reactivity is
really not an issue. This is not a new material. It's been around for a while. And there's been no problem as far as biocompatibility with that material, although I don't think you get any significant amount of debris within the wound.

There was a question about ML placement. And this is, to me, another efficiency area. Notice that the ML position of the femur is placed by using the trial component like a cruciate retaining, and then position it just where you want it, as opposed to many systems which have a separate block which you're guessing the medial lateral position. You can get very precise ML position and notice how Dr. Cherry made it look very quick and efficient. So you just place the femur, ream right through the trial. You don't have to put an extra block on and off. And then you can assemble the PS by just placing the box. This is a very nice demonstration of that.

Okay, so now the engineer in the plan estimated a size 9 and that's what I think it's going to be as well. So we're putting a 9 insert in.

And it's a high flex you're using as well.

Yeah, we're using the high flex knee. You can see we have a nice correction of the deformity.

That looks great.

It's a little wee bit tight in extension, but I'm not- it's not bad considering we started with near 20 greet. Obviously very good flexion. That's the gravity test. He's super solid. You can see, I can feel his medial collateral ligaments nice and taught. Lateral sides taught, and absolutely no soft tissue laxity, patella tracks very nicely. You can see again nice deep flexion. The only thing he has is just a little bit of an extension contracture, which I think is mostly soft tissue. You can see we're pretty close when we started with a 20 degree deformity. So good flexion, full extension, excellent collateral stability throughout. We can flex them up here and see the medial collateral is nice and taut, and absolute stability throughout. So I would say I'd buy that.

Now what's your tourniquet time up to this point? Can we ask anesthesia?

36 minutes. We can show it. It's right behind the table there. We're at 36 minutes.

So bit knee teaching, that's fantastic.

I'll take the other sharp [inaudible] so we're pretty much all prepared now. We're going to just remove components.

I think I'll take the question, then I'll pass this one. I got a question about why choose to use posterior stabilized knees. And I have a little religion as far as PS knees, and I'll give you a very quick answer and then I'll pass it on. Posterior stabilized knees, you can use either. Either work with this system, either work in general. I personally like posterior stabilized knees because I think they bend better. They more reproduce the normal kinematics of the knee better than the natural rollback that you get in a knee is reproduced with the PS knee more consistently. And I think because of that, the more often bend highly. If you want to be a knee that bends to 110, 115, maybe 120, the CR is probably a good, reasonable option. If you want knees that bend over 120, I think from [inaudible] surgeons I think a PS knee would be the better option, certainly over [inaudible]. But, you know I say that as a biased surgeon who likes PS knees. So you can ado either and people can get good results with either. Dr. Cherry, what's your feeling about PS and CR knees?

I was basically trained in Philadelphia where PS was my only exposure. I find, very much like Dr. Haas has said, I think it's definitely an easier knee to the kinematics more accurately. You know the posterior cruciate can be diseased. There's been histological studies that and I do think you
get a superior range of motion with it. To me, it's just an easier, more durable knee to perform
time after time after time. And it's pretty much all I do is posterior stabilized.

And I've tried CR knees and I went back because of the motion issue. But there are surgeons
who get good results. And I think that it's dealer's choice. I notice you to periarticular injections.

Yes, I have a closing cocktail. I do a mixture of hapricen [inaudible] with epinephrine, a little bit of
morphine and a little of actual solumedrol [sp]. And I put it in the soft tissues, mostly in the
posterior capsule on the medial side. And the I irrigate the knee thoroughly to make sure that I
don't really leave any steroid tissue actually in the knee. I want it in the soft tissues only. I think it
cuts down on some of that inflammatory reaction that causes pain. We typically, for anesthesia
use a spinal block and a continuous femoral nerve block that we leave in for about 36 hours. So
the femoral nerve block really gets the anterior part of the knee pretty good, but by putting in this
closing cocktail in the posterior structures, I think it cuts down on their pain and some of their –
that first 24 hours I think is the golden period where patients, if they feel good, they're going to do
good. And if they feel miserable, they're not going to be as excited about their knee. So we try to
take pain control very seriously.

Yeah I think that's a good point. I think that pain control has been one of the big improvements
we've had in knees. And whether you do femoral nerve blocks, epidurals, periarticular injections,
you ought to sit down with your anesthesia department and hospital and figure what is the best
for your environment. I think there will be different options, but it's an important thing to think
about.

Now there was a question about antibiotics in cement. Do you use antibiotics in your cements?

That's a great question. This patient is a diabetic. I don't use it 100 percent of the time, but any
diabetic patient, any inflammatory arthropathy, multiple previous surgeries. So anybody that I
consider to be at a higher risk for infection, we will. This is Palicose [sp] with Jetamycin [sp]. My
routine knees, I just use regular Palicose. But again, if this person being a diabetic, I am using
antibiotic impregnated cement.

There was question about is this only available for Legion. And the answer is “no.” It is available
in Journey, Gen II and Legion. So any of the knee systems you can use it in. And I've personally
used it in both Legion and Journey cases myself. And it's the same things apply, the principles
are the same.

The beauty of it again, as you can see, very minimal bone resection for a notch for a posterior
stabilized knee. It looks like really a CR knee. And again, no violation, no hole in the femur that's
going to drain blood into this knee and into the femoral canal. We've actually looked at that at
Mount Nittany. I have some data that I've reported that shows that we have almost at 50 percent
decrease in blood loss post-operatively. Hemoglobin levels are up 50 percent over the 500 knees
prior to this where we used an intramedullary technique on the femur only. We didn't even do it
on the tibia.

And there are other studies that also show that was so. I think that is an absolutely true finding.
You know even people who put a bone plug in there, but you know it always bleeds through the
bone plug. And that's a great example of how, you know there was a discussion here a bit about
PS versus CR. I think that with some systems it probably is a true point that if you take more
bone when you do a PS. But if you look here, the amount of bone resection from a CR to a PS is
really quite small. And you've left the two condyles connected. It always is, I think structurally
unappealing and aesthetically unappealing when the two condyles are essentially separate. And
from a biomechanical point of view, there has to be some reduction in strength, especially if you
go back. But I think if you've left that bridge, as your femur looks like there, the downside of bone
resection for the PS notch is really I think not really an issue or certainly minimized. We actually
published a study looking at that a number of years ago the amount of bone resection. And in
fact, there was roughly a 50 percent reduction in bone volume with this PS box compared to a number of other designs or some of the classic IB type knee, and so bursting type knee.

I'll take that blunt tip and a clean sponge back in a second, Chandra. It's up there.

You're going to put the final poly, you put it right in?

Yeah, I put it right in. Okay, you pull that out, Jen. Pull that out. Let's just take it out. It's going to be [inaudible] sometimes if I can get the knee subluxated, I'll do it. Otherwise, I'll just set this on.

Yeah, I just pop it in and bring out to extension. And then if I bring it out to extension, I disengage the post cam and boom, drop it in.

Exactly.

It's a nice trick in the many cases. You don't have to lock that poly in flexion. You can bring it out to extension and then snap it and then lock it. And that actually works quite well.

We're going to flex him up here, there's a little bit of cement here.

You get that great compression when you bring that out straight.

Yeah, it really does. I like especially when we have limited exposure, I like to just flex them up and make sure that I don't leave any cement here on the side just one time. Clean sponge. That looks good. I want to thank the crew for helping out. Chandra was my scrub tech today, did a great job. Jennifer, my PA, assistant, Shelly, second assistant and Carol was the circulator. So thank you for a good job.

Ken, do you usually have two assistants at the table with you?

Yes, I usually have my physician’s assistant. Typically, we run two operating rooms. On a typical day I would move over and start another knee with another physician’s assistant. And Jennifer would stay and close this knee now and I would be started on a new knee in a few minutes.

It's nicely choreographed, some of the maneuvers, which is think is a goal of all surgeons. You want to minimize hand motions, minimize unnecessary activities during the surgery. You want to do all the important things but not do the unimportant things that are wasting time for the patient on the table.

So yeah, we are cemented on what I felt was a pretty difficult knee at 46 minutes.

I think you have shown there and I think it's so important, you don't want to have time for the sake of being fast. Fast is not what you want but efficient is that you want. There's no reason to waste time doing things that don't add to the operation and just leave the patient's knee open longer. So whatever that time is that you need to do everything, all the steps you need to do, the reason why I think this is nice is there's just simply fewer steps. If there's fewer steps, that's where you save the time, as opposed to skipping steps. You're not skipping things, you just combine things together and eliminated the need for drilling the canal, putting in additional guides onto the knee.

We typically won't use a drain unless there's a reason. I've found that, again, by not violating the intramedullary canal, the bleeding is considerably less. So we save the hospital on not requiring a hemovac drain in these cases. Again, our transfusion rate is considerably lower than it had been before. And so, looking at time saved, transfusion rates lowered, actually pain mediation and rescue pain lower. We're starting to kind of categorize all this and give them a number that
we’re saving the hospital actually money even though the up-front cost is a little bit for the blocks. The overall savings is considerable.

Ken, do they donate antilogoous blood for the operation?

No, we do no auto blood here at all. We sometime will look, if they're anemic pre-op, try to elevate their hemoglobin preoperatively. But other than that, no blood donor program at all.

Ken, describe a little bit about the post-op rehab protocol.

Okay. Patients have a femoral nerve block in place. They get up with the knee immobilizer mostly just because of the femoral nerve block. They'll weight-bear as tolerated. Our typical post-op day one, knee flexion is between 90 and 110 degrees. On the morning of the second day the block is removed and the patients are sent home. Our length of stay here is just over two days, 2.1 days. And we expect at least 100 degrees of flexion and their ability to ambulate independently at that point. Once they go home, an average physical therapy patient is about three weeks of therapy, nine total sessions. By nine total sessions, most patients can ambulate with or without a cane, but nothing more than a cane. And they've achieved at least 110 degrees of flexion.

Ken, I want to thank you and your team for doing an absolutely fantastic job, a beautiful surgery. And I want to thank the audience for participating and appreciate the questions that were asked. This will be on the ORLive site for those who want to watch it again. It will be able to be viewed. I want to thank everybody for viewing tonight and being with us in State College, Pennsylvania. Thank you very much. Good night.