

I'd like to introduce to you T. J. Whitaker who is a physicist at Kennestone WellStar in Marietta, Georgia.

T. J. got his PhD from Indiana University and has been doing medical physics at WellStar for a little more than a year now, I think, where he primarily specializes in CyberKnife, but is also, at this point, one of the world experts in electronic brachytherapy.

DR. WHITAKER: So I have the flashbacks from wedding talks and - a little nervous, my heart comes through my chest just - you know, call my wife, I guess. So I'm from Kennestone Hospital and we've treated five patients now. So I think we are well in the lead in this modality of breast brachytherapy. So for this talk I'm going to give you a quick treatment overview, go through our pre-treatment QA, some treatment monitoring that we're doing, and then I'm actually going to step you through, probably, the more interesting part of the talk, is walk you through an actual failure of the x-ray source during patient treatment and the recovery of that. So I'll be kind of highlighting the differences or the things that one would be looking for if they were doing lots of MammoSites. What they might expect or want to keep their eyes out for if they were to add Xofter to their repertoire. So here is - you like that repertoire, I like that. So here is just a step through of what about - to talk about in the treatment work flow. Pre-treatment QA of the patient source, of course, pre-treatment imaging of the balloon, verification of the patient identity, of course, that's always very important. We'll load the dwell times, calibrate the source, double check the temperature and pressure and I'm going to say that about five times during this talk, that's going to be a big thing, and verify proper dwell time adjustment. We'll align the controller, place shielding for the benefit of the patient and then shielding for the benefit of the operator and then will start the treatment. So what does that look like? Okay. So, more or less, let's start with the imaging. I've been told from other sites that they've had good imaging results with the Xofter balloon under a simulator situation, we have not had as good an experience with the Xofter balloon for a simulator. CT, you can tell, it works really well. I think there might just be a little bit of lapse. I think most of us know that patient size now is bigger than people really think it is, and so when you put a realistic patient on the sim table, it is difficult to see the Xofter balloon. So you will want to put these on the CT more often than you would your MammoSites. The other thing to add here is it is important that the Xofter balloon not get contrast put into it. And so one thing you'll need to do is to make sure you have good communications with your surgeon and you, personally, need to keep an eye out. We did have a patient show up with contrast in the balloon and because of the low energy of the photons, that has a devastating effect on the treatment. We do a lot of MammoSites. We were almost done siming the patient before it - I just - something just didn't look right. We were almost done siming the patient and I was like, "Oh my gosh, she's got contrast on the balloon." So, you know, you'll want to have that in the forefront of your mind as you move to this treatment because you will have a surgeon just forget. Their team will put the contrast out on the table and the surgeon will put the contrast in the balloon and you'll just need to make sure that you handle that situation appropriately. And then, again, it helps to have very good relationships with your surgeon, so that those things can be handled appropriately and quickly. We were able to bring that patient - send them back to the surgeon and get the patient back and finish the planning that day still. So here's just kind of a diagram of the pre-treatment process. This would be where we would load the dwell times. It's also a good time to - do I get a mouse cursor thing? No. It's also another good time to verify up here, the patient you think you're treating and the dwell times that you have just loaded, that these two names match, especially if you have more than one patient under treatment at one time. This is

a blow up of the calibration chamber. Here I'm just actually doing the calibration. Here's a picture of the screen of the result, so it gives you an air-kerma strength of what you just measured. It goes ahead and attenuates for the barium in the balloon and comes up with a time factor to adjust the dwell times. And then the dwell times are now adjusted and we can verify that it has come up with the right values. Here's a patient setup. Here's our surgeon; he was magically there for the first day when the pictures were being taken. I knew I was going to get a good laugh on that one. But in all honesty, the relationship between you and the surgeon is very important. And we do a lot of MammoSites. We had no problem getting patients onto the Xofig trials. It all has to do with having a really well-networked patient flow through the system. So if any of you have difficulties in getting patients for this type of treatment, my guess is work on the relationship there. Here we are setting the patient up. You can see there's the control arm and the source and the balloon. FlexiShield and Tom Rusch, for those who know him, he's setting up some monitoring. Here's a closer view of the balloon and the FlexiShield. After a treatment or two, we kind of changed our minds on what the FlexiShield's purpose probably ought to be. We don't really feel like it is really for us, the person standing on the other side of the source, but should better be placed to shield other portions of the patient's anatomy that we might want to reduce dose to. Here is the placement of the rolling shield and we have a nice clear one; it's really handy. Here would be just a - loading up of the dwell positions, loading the source to the first position. And then here's what the screen looks as you complete the treatment. Okay. So, pretreatment QA, we use the jig that Xofig gives you for QA and other tools. We have a QA treatment plan of 15 dwell positions spaced every 5.0 mm, 5 second dwells. The jig has a port for either a Farmer or an A16 chamber. We put an A16 chamber in there, and we externally read it out with a Max 4000 Electrometer. So here's the setup. The nice thing is the jig is completely shielded, so you can sit there, and it's got a clear top, so you can actually watch it go to each dwell position and you can see the markings - and yeah, that's probably all I really want to say, just some pictures. So here is the results, what we call a fingerprint of the source. To note here, it's very repeatable. You can - I don't know that it's obvious that it's really repeatable, but we truncate on the first dose seen by the electrometer and we've done nothing else, essentially, to any of these curves. So this is, essentially, raw data. It is raw data. There is one curve that sits out. This happens to be that, we did not put in a temperature and pressure correction for the QA we did for the patient. But on this day, it was left out before we delivered the QA treatment plans. So you can tell how big of an effect, depending on where you live, forgetting to put that temperature and pressure correction is; it's totally shifted. The other thing you can notice, and this is not completely flushed out yet so I can't show any of, some of the calculations that I've made, but the height of this shoulder here is sensitive to position. So I'm not exactly sure, quite yet, how good of a test of position it is, but it might be that we can have very good position tests based on that shoulder height. So I think this is a reassuring slide and I'll show you a normalized version, which will be a little bit more obvious. But you have two outliers in the graph. These, as I looked back through all of the treatments, these were due to improper temperature and pressure corrections. Everything else follows, more or less, straight. And this is the integral dose of those curves I just showed you. So I just summed all the values. Here's a normalized version so we can see that the pretreatment QA shows you that the source delivers the same plan within a percent, unless you've done something wrong. In our case, the easiest thing was to forget to put the temperature and pressure in, so that's why I keep saying that. Here is just a plot I made of the dwell time correction factor; of course, this is essentially the calibration of the source and the temperature and pressure together. And you can see that the source is relatively stable through all treatments.

Most of the sources - this is our five different patients. Most of the sources were very stable the entire time. We do see that every once in awhile there might be a jump on the source. And so my recommendation would be to simply track these values and when you see a jump, repeat the measurement a couple of times and make sure that the calibration is solid and you haven't made a mistake somewhere. And also, Xoft is, I think, soon going to be adding a check source. So you'll have another way of verifying that you're in the right ball park. Not the right ball park - that you're doing the correct thing, I mean. We are calibrating the source everyday. And I know that, that is the biggest - has to be the biggest anxiety to the physicist, "How do I know what the activity of the source is going to be, when it's not a chunk of metal that I can depend on?" So the source is stable, but I would track it, just because we all want to sleep at night. We did do some patient monitoring. Because this is the first clinical roll out, we wanted to add a few extra things to make sure that we were doing all we could to make sure that we understood the system fully. We used either a pancake probe next to the patient or a Sun Nuclear diode on another occasion, and, again, externally read that out with the same Max 4000 Electrometer. The lead physicist, mostly on this project and in the department, wanted me to point out and make sure I point this out, that he would suggest placing say a diode here or here, inline with the direction of the movement of the source. And the reason for that is if you do that you get a nice set of stair steps corresponding to the dwell times. The electrometer we're using, we just set it on max sampling, so I can't guarantee that I know what the sampling rate is, but say you have an electrometer where you know the sampling rate, well then you would have a very nice independent measurement of the dwell time being treated appropriately using this during patient treatment monitoring. Okay, so now what everybody wants to know, what happens when things don't go the way there supposed to? So here is a treatment of one of our patients. This is from the log files. There's a log file for every treatment, which shows beam current voltage, the dwell position, the time you spend at that dwell position. And it's sampled on a regular basis. I don't know that we know the actual sampling time there either, but there is a clock, and that's where I get this value here in the log file. So you know where you're at in time from the log file. So this is a treatment of a patient that went without a hitch. So here this red curve is the beam current and I assume that when the beam current is at its peak, that's where all the dose is being given, and I don't think that's a bad assumption. So you can see that the - right here the beam current was nice and stable the entire time of 446 seconds. Of course, there's a calibration factor in there, so we need to renormalize this, if we're going to compare this to any other treatments for this patient. That's what this little bubble down here is. I take out the calibration constant and go to a nominal time of 400.7 seconds. Okay, this did not go so well. We were able to treat 14 seconds and then there was a tube failure. We went through the recovery process, which is actually very easy. Came up, treated 96 seconds and then there was a tube failure. Then we switched sources and were able to finish and complete the treatment of 314 seconds. So each one of those treatments has a calibration constant. If I go and I normalize each of those sets of events and then add up the total, low and behold, 400.5 seconds. I think that is rather amazing, honestly, I mean, that's just incredible. So recovery works quite well and is reassuring that, you know, it is possible that these tubes will not make it through a treatment once or twice during a patient's full course of therapy, but it's good to know that the patient is going to be treated properly anyway. So, in conclusion, pretreatment QA has shown that the source is stable. We have repeatability of dose delivery. Temperature and pressure verification is very important, I think, for almost everybody in the U.S. And then, I do believe that we will have some good position information, but that's just not flushed out yet. Treatment monitoring shows that it is good and stable during treatment, and could

possibly, depending on your set up in your clinic, have an independent dwell time verification completely independent of the device itself. Sources may fail, but they do recover the dose accurately. And I would like to make just a brief mention on the source failure. As it is right now, the source is being recommended to be used one source per patient, and of course we are using it in that fashion as prescribed. We are recommending to Xoft that they push to have it one source per X number of treatments. The failures seem to happen when you swap sources. And so, one needs to be very careful and conscientious at swapping sources, not to add any contaminants to the connection and things like this; this is what makes the sources prone to fail. So if you're going to be treating lots of patients, we are recommending that we go to a one source X number of treatments, rather than that. And I think that will increase throughput and also will get rid of the source failure. If we do that, then I don't think these things will ever fail, very, very, very rarely. So - and that's all I've got.