Oral History with Dr. Sally Friedewald, July 27, 2020
Interview by Benjamin Spohn for Hagley Museum and Library
Hologic oral histories project

Q: So today is July 27th, 2020. Today I am interviewing Dr. Sally Friedewald about her role in breast tomosynthesis and the history of medical imaging. So thank you for taking the time to sit down and speak with me today.

[00:00:21]
A: Thanks for having me.

Q: So, just to get us started off, can you tell us a little bit about your sort of early life and education? How did you get to the point where tomosynthesis was something important in your life?

[00:00:38]
A: Sure. So I did all of my medical training on the east coast. Went to medical school at Columbia University in New York City. And then did my radiology training at Johns Hopkins in Baltimore, and did my specialty training in breast imaging at the University of Pennsylvania. So I have done a lot of training for radiology. But specifically, my area of expertise is breast imaging. And I ended up taking a job in Chicago because my husband was recruited to Northwestern for transplant.

[00:01:19]
So he wanted to come out here to Chicago, and I followed with our one year old child. And I was in private practice for a while. While I was there in private practice, I attended several conferences. But one stands out in particular, at the RSNA, which is one of our biggest radiology meetings, really in the world. And this was early—well, I should say late 2000s, so maybe around 2008 or 2009. And I attended a meeting where they had a new technology that was near ready for serious research evaluation that seemed to utilize an older technology, tomosynthesis, and apply it to breast imaging.

[00:02:13]
So I attended this conference and I thought the images looked great. And I reached out to the maker of the platform, and said that I wanted to get involved in research. Since I was in private practice, I didn't really have a foray into research in the academic environment. So going straight to the vendor was very advantageous for me, because I was able to talk to them about their specific technology.

[00:02:39]
And they were starting up a trial, so I was able to get a research unit installed into our hospital. And we started collecting images. Because we were early on in this research project, and were submitting images for reader studies, et cetera, when the technology became FDA approved in 2011, we were able to convert our tomosynthesis unit to clinical use. So it was a research unit pre-FDA approval, but we just needed a software upgrade so that we could use it on patients.

[00:03:17]
So we were able to image a lot of patients. And because of that, we were the fifth site in the country to utilize the technology in the clinical setting. We got a group together to study the effects of tomosynthesis on real live patients, rather than just in reader studies. So it was very exciting. It was incredible timing to be involved in this new technology, and then to be able to purchase a machine right off the bat, really allowed me to get very involved in the technology.

Q: Can you share what drew you to the field in the first place?

[00:04:03]
A: So I actually really originally wanted to be a surgeon. My father was an anesthesiologist. So I spent a lot of time with him in the operating room. And I really liked the procedure aspect of surgery. But realizing that it was a very demanding field from a time standpoint, and I knew that I wanted to have kids at some point, I felt that probably radiology would be a better fit for me.

Radiology has some areas called interventional radiology, where you can do a lot of procedures. But it seems like it's a little bit less time-intensive as general surgery.

[00:04:42]
So I ended up doing a year of surgery internship in Baltimore, before my radiology residency. And we have to do a year of clinical work. Most people choose medicine, but I chose surgery, which was allowed. And just to make sure that I was making the right decision by going into radiology. And I discovered that pretty soon after my first day, that I had made the right decision going into radiology.

[00:05:06]
So I was planning on doing interventional radiology, which is a subsection of general radiology. But when I started doing my breast rotation, I realized that I could do procedures, have the patient interaction, and it really, I felt like I was really contributing a lot to patient care. Some of the other areas of interventional radiology, you don't really see how patients do long-term. And so it really wasn't quite as immediately gratifying to me. So I chose breast radiology, which really is a phenomenal field. And just very happy I chose it.

Q: Other than tomosynthesis, which of course we'll get to, have you experienced any other major advances or changes within your field?

[00:06:06]
A: Well, I think I am dating myself a little bit. But when I was training, back in 2003, I joined my Fellowship in breast imaging, we were still reading off of film. So we went from film, which had to be developed in the developer, and you only get one copy of it, to digital. We were sort of transitioning to digital around that time. But I learned on film. And then, when I went into practice, had to learn digital mammography, which looks very similar, but certainly allowed for a lot easier interpretation and distribution of images, because you have more than one copy, you have infinite numbers of copies, which is really critical in breast imaging.

[00:06:53]
We do so much comparing to prior examinations. And that really allows us to limit the amount of unnecessary imaging on patients, if we have the prior exams. So the digital mammography, although helped a little bit, in terms of cancer detection, really facilitated the comparison of those prior films, and patients transferring to different institutions. So operationally, it was a huge advancement.

Q: So did that cut down on the time you had to spend per patient? Or no, I'm not sure I like the wording of that. Can you walk me through a little bit about what sort of the user experience was for you as the doctor?

[00:07:44]
A: It really is much nicer to have everything on a monitor. And to be able to easily switch back and forth between prior exams, current exams. With film, you have to have somebody load it onto a machine. And that machine will move up and down, depending on which images you want to look at. But there was a lot of manual manipulation, which was very time-consuming. And you really were dependent on a person to hang those films for you. So you couldn't really look at an examination until the images were hung.

[00:08:18]
And so now, pretty much instantaneously, after the examination is acquired digitally, they're available for the radiologist to interpret. So I think just, again, operationally, digital mammography really transformed breast imaging. Our other modalities, such as ultrasound and MRI are also digital. So it really just makes the most sense to have everything together.

Q: Did you have to deal with any infrastructure type challenges during that switchover? I know some of the other folks have talked about that they bring that up.

[00:08:55]

A: With any new modality, or any new advancement in the field of radiology, specifically breast imaging, requires a huge financial investment. And it is very hard to work in a, what I call a hybrid environment, where you have some equipment in one form, and other pieces of equipment in another form. So for example, if you were—if you have half a million dollars, and you can buy a new machine, then you can take one analog film machine and transform it to digital. But we have 18 mammography units in our one facility here. So it's hard to switch over all machines all at once. Just the financial outlay of money is really just enormous.

[00:09:50]
So it's unusual to be able to flip everything overnight. And it's true, even just with software. So it's not just the hardware. If you get improvements in software, it costs money. And so, for example, right now, we have a higher resolution synthetic imaging, which I can talk about later. But it's just a software program on about half of our machines. And so it's very hard to compare the older version and the newer version.

[00:10:15]
So we really like to have everything as uniform as possible. But that's just not the reality. So whether it's hardware or software, there's always a time period where you have to be a little bit more flexible, and realize that some of the findings may be more obvious, allowing for differences in technique and different modalities.

Q: So when you had to learn these new methods in practice, who taught you? How did you learn?

[00:10:50]
A: Well, I mean I went through a lot of specialized training. So as I mentioned, I did a whole year of Fellowship in women's imaging. So you learn in your Fellowship. But then, as things change moving forward, it's important that you keep up with the societal meetings, and the journal articles that get published. And that it's much easier to do that in an academic

environment. We have conferences every week. And people bring up, “Oh, this article talked about this.” And you incorporate it. And you learn from each other.

[00:11:22]
When you're in private practice, it's a little bit more isolating. And it's not that you can't do that, but you have to be more proactive about it. It's not just going to passively come to you. You have to really seek it out. And so it really takes a special person who's motivated to keep up with the technology. In terms of the digital training, the FDA requires eight hours of formal training when we moved from analog to digital. So we did that. And with tomosynthesis, the same thing. I was trained by somebody who was also very early on in the field, to interpret the imaging and how the technology worked.

[00:12:03]
I have subsequently now taught a large portion of the country, this eight hour training that's required for tomosynthesis. So once a modality comes out, usually training gets developed pretty soon thereafter. And if it's required by the FDA, then we—usually vendor-supported. But if there isn't a specific vendor, then the American College of Radiology will provide training for radiologists.

Q: And what does that training actually look like? Did you get to travel around to different care providers, and do it in person?

[00:12:42]
A: Yeah. So specifically, since I did a lot of training for tomosynthesis, I have traveled internationally to do those trainings. But I've also done it in the comfort of my own institution, where I've done it virtually. So we have in-person training. We have WebEx training, meaning we can do this via WebEx. And then there's the virtual training, which it's a recorded version of our lectures, and the cases are available on their own computer. So sort of three different methods. And it's usually a mixture of actual lectures. So we would usually have about two to three hours of formal didactic training. And then a bunch of cases that we would have the student

review first, and then I would go over the cases individually with them, with all the findings, so that they could get a feel for what to look for, and determine whether they could find it on their own.

Q: So was that like a literal pass/fail test, like, "Can you read these images?"

[00:13:59]
A: In fact, there was no grading. It was really just mere attendance. So for being present for the full eight hours of training. I also—So that was what I have done through our vendor. But I've also done a lot of training with the American College of Radiology, it's something called boot camp They have boot camps for all different modalities, imaging modalities. But I would say the breast imaging boot camp is one of the most popular. And it's because the FDA requires a certain number of cases to be read prior to being allowed to interpret mammography.

[00:14:38]
And so during this boot camp, it's a three-day course. We have over, well over 700 cases that the students can review on their own. And we as faculty are available. So we give lectures sort of intermittently throughout the day. And then we sit there waiting for the student to ask us specific questions about the cases. So they could get through as many or as few cases as they would like. But it's really just—And again, also don't have to pass or fail, you just have to get through that many cases.

Q: Okay. Were you involved in the development of any of the training courses?

[00:15:27]
A: Yes, very involved in the development of the eight-hour course provided by the vendor. In fact, I worked with two other radiologists on collecting cases. And we each took a portion of the didactic training lectures, and delivered them. So, for the virtual training, meaning the one that was recorded, we all had our own lectures, and then helped develop the key, if you will, for each

of the cases that we provided, so that we would point out the findings and write up exactly what they were, and what they ended up being after biopsy.

[00:16:12]
For the WebEx training, which was live, but I had probably 80 or so attendees on each of the WebExes, I gave all of the lectures, and then provided all of the answers to the specific cases. So very, very involved in that training. Really loved that experience.

Q: And how did you go about selecting the representative cases that students would--?

[00:16:43]
A: So the three of us, Steve Rose and Linda and I got together. We basically had a, I don't know if it was three or four months time period, where when we were reading our patients, our normal exams, if anything seemed interesting or represented a specific finding that was important to teach, we would write down the patient's name and collect those cases, anonymize them. And then, Steve, Linda, and I, as well as some other people from the vendor, got together on a weekend, and we had over 500 cases. And we sat down and basically graded each case as to whether we thought it was excellent example, moderate, or not really a great case.

[00:17:35]
So we basically ranked them all, and just took our top—i think it was out of five. And we took all of our best cases for each of the examples, and pared them down. It took us forever. But we really had some wonderful cases. So cancers, and benign findings, and reason why you don't have to call things back anymore. So it was really an incredible spectrum. And in that—that, in and of itself, taught me a ton, because I got to see a ton of cases just in the very beginning, where you had pathology that was proven by biopsy. So we knew exactly what it was. And so I learned an enormous amount, just in developing that training course.

Q: So I've heard that—not that the field is conservative, but that it was— mammography was one of the last medical imaging fields to switch from film to digital.

A: Yes.

Q: Okay. Do you know why that—Do you have any insight as to why things played out that way?

[00:18:45]

A: I think, I think it was largely technological. Mammography requires really, really high resolution imaging. And the other modalities, such as CT, ultrasound, MRI, that's all digital information to begin with. So, and the resolution isn't nearly as high. Now the chest x-rays, so x-ray, in and of itself, requires high resolution, but not quite to the level of mammography. We're really trying to find things that are very, very small, and require enormous detail. So I think that was probably the biggest reason. But then, it really requires organization. And mammography is regulated heavily by the FDA. And so it required a lot of organization to get that through sort of the regulatory bodies as well.

Q: About how long?

[00:19:55]

A: Well, digital mammography, I think was FDA approved in 2001. So it all started before then. And so, as I mentioned, when I was a resident in the early 2000s, at least at my institution at Hopkins, the neuro section had switched over to digital, but not really the other modalities. So it was a gradual transition. Interestingly, though, it took a long time for sites to switch from analog to digital, even though it was FDA approved. And it was a much slower uptake. So that after about five years, there was only a small percentage of mammography units in the country that were digital, compared to tomosynthesis, for example, which changed very rapidly.

Q: Why do you think the changeover from digital to tomo occurred so much more quickly?

[00:21:00]

A: I think it was partly because of our research, and we showed that we really were detecting cancers at a—certainly a significant, you know, statistically significant increase, as well as decreasing the number of abnormalities that we did not have to call back. Whereas digital really, as I mentioned before, was really more operational. So it was nice to have it. But there was only a very small subset of patients that actually benefited more with the digital. And that was pre-menopausal women, women in their 40s, it showed a slight improvement in detection of cancer.

[00:21:39]
But with tomosynthesis, it was really for all age groups, all tissue types, benefited either with increased cancer detection or decreasing recalls. So we were really providing better standard of care with tomosynthesis than I think people recognized that. And, because we were calling fewer people back, it was a more efficient way of looking at imaging. And we didn't have to have patients come back for unnecessary testing, which I think saved the system money. And that was a huge impetus. So investment in the beginning with the equipment, but overall healthcare savings.

Q: And does tomo give the patient a significantly higher radiation dosage than other methods of imaging?

[00:22:30]
A: It depends on how you image the patient. But if you acquire both the 2-D imaging and the tomosynthesis images, it is about twice the amount of radiation, but still well below the FDA limit of three milligray. So it was still safe to administer to patients. And I always like to point out that analog, or film mammography, was still pretty high. So we were able to bring down the dose with digital, and then it went back up again with the adding tomosynthesis, but overall still quite low. Now we have synthetic imaging, where we can generate a image that looks very much like a standard digital mammogram without having to expose the patient to that dose. It's generated from the tomo data set. So our actual doses now are equivalent to digital.

Q: That's another thing I've been told about, is that mammography, as a big annual chest x-ray, is kind of unique among other screening methods.

[00:23:43]

A: In that the amount of radiation that they're getting? I'm not sure I understand what you mean.

Q: Yeah. This was concerns going back to early 1980s. Oh boy. See I don't have that specific set of notes in front of me right now. So I'll just—I'll just leave it for the moment.

[00:24:08]

A: Yeah. I mean I think there's a lot of misunderstanding about the radiation dose to the breast specifically. I think people are concerned about radiating breast tissue, because, you know, it's a sensitive organ. But I always like to remind people that we know that the risk of developing breast cancer is extremely high in patients who have been radiated for treatment purposes. So, for example, if somebody has had lymphoma, and they need to get chest radiation, because of the lymphoma, those patients have a high risk of developing breast cancer. So I think people get a little nervous about, you know, you're going to cause my breast cancer by radiating it.

[00:24:55]

Well, it's interesting to note that breast tissue itself is radio-sensitive when it is developing. So the tissue is still rapidly evolving and maturing over time, pretty much between the ages of 10 and 30. and we know that—Or, the exception to that is, if the patient gets pregnant, their breast tissue rapidly develops during pregnancy, in preparation for lactation. So it's really that changing or maturing tissue that is radio-sensitive. When patients have had chest radiation because of lymphoma, their risk of developing breast cancer is high during this maturation process, basically between the age of 10 and 30.

[00:25:42]

They get the same amount of radiation after the age of 30, they don't have any increased risk of developing breast cancer. So the breast tissue is not as radio-sensitive after age 30, or after the

patient has had a child. So that's why we typically don't do mammography in women under 30, because of that radio-sensitivity of the breast tissue. After age 30, it's really no different than any other part of the body. So it's like getting a leg x-ray or a hand x-ray. And so the breast tissue itself is not as sensitive.

Q: See, I did not know that. So how much lower is it compared to, like, radiation for—You were comparing it to radiation for cancer treatment, right?

[00:26:31]

A: Right. So, I mean, it's just a tiny fraction And we always use the analogy of flying across country a couple of times. You get cosmic radiation when you fly. And you are spending a lot of time in the basement, as my kids do, on their video games, especially during this pandemic. There's radiation that they get, or anybody who spends time in the basement. So background radiation is around us all the time. And you know, as I mentioned, a single exposure with tomosynthesis is still below three milligrays, really, really tiny doses.

Q: Actually, if I could shift topics for a quick second, and just go to the side with some really just over the shoulder type history. You mentioned the pandemic. Has that—Have you noticed that that has impacted people's willingness to go out and get these sort of preventative screenings?

[00:27:33]

A: Well, it was really an interesting time when this first came about in March, when we realized that we were going to have to shelter in place with the regulations in Illinois and Chicago. We were only doing really high acuity cases. So we stopped screening altogether And we were only seeing patients that were very suspicious for malignancy. And any acute problems, such as abscess or, you know, patients that had a fever because of a breast infection.

[00:28:14]

But, as time went on, and we realized that we just couldn't prolong the screening or the less suspicious cases, we started opening back up towards the end of May. And now we're back to full capacity. And it's interesting. We are seeing reluctance of some patients coming back. And we've seen some cancers that have been sitting around since March. So I don't think that we can shut down again. I think that, even if we have a shelter in place order, it's unlikely that we will shut down completely like we did before. I think we'll probably still operate as normally.

[00:28:55]
We've been able to accommodate our patients now by spreading out our appointments. So we have far fewer patients coming in all at the same time. We've extended our hours, and are doing a lot more imaging on the weekends, so that we can have patients socially distance, while getting the care that they need in a very safe manner.

Q: That's interesting to hear how these things have evolved across different states. Because, you know, where I'm at, you know, Hagley is very close to the Pennsylvania state line. So about half our staff, myself included, live in Pennsylvania. So like during those early days, it was like, you know, we were told not to come to Delaware at all, because the Governor had an out of state quarantine.

[00:29:50]
A: Yeah. It is all very interesting.

Q: So what would you say was the—Sorry, I need to think of my words for a second. Which would you say is more difficult for a care provider to learn how to do, to read the digital images? Or to read a tomosynthesis scan?

[00:30:20]
A: I think a digital can often be indistinguishable from a traditional analog film mammogram. So the transition to tomosynthesis was definitely greater, and required a lot more teaching. I think there really wasn't a ton that you needed to learn when we switched to digital.

Q: Related to digital, I'm aware that in the film days, that there were sometimes films that had like different color tints to them, and that that was kind of the, at the preference of the person who would be reading the image. So with the digital image, could you sort of apply your own tint to that?

[00:31:10]

A: Yeah. I mean, and there really wasn't any choice. There was no manipulation of the image on film, because it's what you got. You know, I think you're used to your specific developer on paper and all of that. So you kind of get accustomed to what the facility has. But with digital, you could manipulate the image to your liking. That being said, I almost never do that. Theoretically, you can kind of make it look how you want. But after a while, you just get accustomed, again, to how it's presented. And I think a lot of your choice in manufacture of the equipment has to do with what its sort of default appearance is.

[00:31:56]

So I tend to like this one manufacturer that we use. I like the way it looks. And so if I went to another facility that had a competing vendor's equipment, I think it would be very hard for me to switch over. I probably would, after time, get accustomed to it. But you tend to gravitate towards what you're used to and what you like.

Q: So how strong is brand loyalty within the field for something like that?

[00:32:24]

A: I think it's pretty strong, although, I mean, I have my personal opinions about the equipment. I think, again, you tend to like what you trained on. Some people are a little more flexible with that. But I would say, in mammography, it's a lot stronger than it is, say, for example, an ultrasound or other modalities. In ultrasound we have switched around a fair amount. I think there's a lot more manipulation of the image appearance. And you kind of work with a vendor to

set how you kind of like it to look. But it needs to stay that way, because it serves as a reference point.

[00:33:04]
So, for example, if you, like, for example, a mass to look a certain way, then when that patient comes back for a follow-up exam, you want to make sure, if you start changing the parameters too much, it's going to be hard to compare it, year after year. So you really kind of have to pick an overall appearance of what it looks like, and then stick with it. And when you have 14 different radiologists, it's sometimes hard to come to a consensus. But eventually, you do.

Q: So that is like my next follow-up question, was how do you come to that consensus within a department? Is it just as simple as like the most senior person gets to pick? Or you take a load? Or?

[00:33:50]
Well, I'm very democratic. And so I'm section chief here, so I am in charge of the section. And so I ask people's opinions. But a lot of it is just experience. And I don't mean like years of experience, it's, well, this looks like a mask. But then, when I tried to biopsy it, it was a cyst. And so I think we have the setting too much in one—this is, I'm thinking of ultrasounds specifically. But the settings were set too much to make it look like a mass, when it really was a cyst. And so we changed the parameters a little bit.

[00:34:26]
So it's sort of reinforcement based on biopsies, really. And then we kind of tweak it until we get it to a point where we feel like it's the truth. It's really always speaking the truth and not over-calling things as a mass, versus over-calling things as a cyst. I mean the worst thing you can do is have the setting such that it makes masses look like fluid, and you say it's benign, and it's actually malignant. So we really don't want to do that. So it's just people playing around with the equipment, and showing each other. And we just sort of gain consensus that way.

Q: So I think that the next question is probably going to be the really big one for this interview. So what was it like to set up that research unit, to come across tomosynthesis, and then go back and say, “Hey, let's do this,” and then getting the go-ahead or permission and interest to set up a research unit in the hospital?

[00:35:34]

A: Oh, it was life-changing for me, really. I mean I really wasn't thinking that I wanted to go down the academic pathway. I was really happy in my private practice, which typically, when you're in private practice, you don't do much research and teaching. But it just so happened that the hospital where I was working, although it was a private practice, it did have a research department. So they were a little bit more hybrid than some peer private practices.

[00:36:03]

And so I worked with the research department to, as I mentioned, to get this research unit in. and the hospital was very supportive. So I feel very fortunate. I was really lucky that all the stars aligned, and we were able to get it in. And people were very—Some of my technologists were a little reluctant, because it's just more work that tends to not be compensated. And so it's just added effort. But I do think that, in the end, people really recognized that this was on the cutting-edge of breast imaging, and that we were really going to be helping people.

[00:36:39]

And I think that always motivates, even the greatest naysayers, people who don't like change, when you really see with your own eyes how something could have been completely missed on a standard mammogram, but is clear as day on this new technology, it just, it caught on, and people were really enthusiastic about it. So very excited to have that in the department. And then, was equally excited to have the hospital choose to invest the money to purchase the machine outright.

Q: So it sounds like, once you had the machine in place, you didn't need to cheer-lead for it. It kind of was able to take care of itself.

[00:37:32]

A: It was. It's very dramatic, the images that people were looking at. And really, the first week we had it clinically, I found in the same patient, two different cancers, one in each breast, that had not been detected before. And we were simultaneously imaging with the 2-D imaging and the tomosynthesis. So we could really compare. And you could not see it on the 2-D imaging. So we called it tomo-only cancers. And it's just, it's scary. All of a sudden, it got to the point where we felt uncomfortable reading patients that just had the 2-D imaging.

[00:38:08]

And part of the reason why, you know, to go back to some of your earlier questions, part of the reason why I liked the technology so much was that I thought that it would be easily accepted. And it's because you weren't taking anything away. It wasn't like we were taking information that we had before, and starting with something completely different. The technologists were positioning the patient in the same exact way. The equipment was nearly identical, except for one part. It just moved a little bit on the second half of the imaging.

[00:38:43]

And so their transition as technologists was almost seamless. The patients weren't going to notice, really, anything different. And then the radiologists had their old imaging that they relied on all the time. And they just have add-on. They had new information that helped them make decisions. So I just felt like it was so much easier to implement in an environment. And I thought that it was really going to take off. So that was a big reason why I felt like this was really going to be unlike anything else. It's not like bringing in MRI, which is a totally different modality, that requires so much, you know, understanding of the technology. And we don't have the processes in place. So operationally, it was just going to be easy to implement.

[00:39:31]

So because of that, so it was super easy. It was just a few seconds longer for the patient. It was the same positioning for the technologist. It took a little bit longer for the radiologists to read.

But the cancers that we were finding were dramatic. And so that was really [00:39:48] if you will. I mean don't get me wrong. It took—It was kind of a hard sell for radiologists because it did take two to three times as long to read the exams. And we weren't getting any additional payment for that. And so that hurts.

[00:40:02]
And so normally, if you're spending two hours reading screening mammograms, it turned into six hours, that's a tough sell. But if you were, you know, the radiologists that were really invested in patient care, realized it was a necessary process But that then pushed me into realizing I really had to advocate for coverage with insurance companies. Because otherwise, it just would be just a huge financial hurdle for us to get over.

Q: Okay. Wow, I've got a bunch of follow-ups. [laughter] So you used the phrase "tomo-only cancer." Is that a function of that tomo can pick up cancers when they're much, much smaller? Or is it just a bunch of different factors all across the board?

[00:41:02]
A: It's all across the board. So we have cancers that we can see on both modalities, digital mammography and tomo. And then we have what we call the tomo-better cancers. These are just colloquial. They aren't really any official language. Tomo-better cancers, meaning we can see them much better on the tomosynthesis. But looking at the 2-Ds, you can see it. It's there. It probably would have been picked up. But maybe not. I mean it's kind of hard to see, in retrospect, you can see it. And then the tomo-only cancers is truly only seen on the tomosynthesis images, and not at all detectable, even though you know exactly where it is, you still can't see it on the 2-D imaging.

[00:41:39]
And in terms of the function, I mean I think it's both. I think we're finding cancers much smaller than the traditional 2-D mammography. But I've seen huge cancers that you can pick up that are

tomo-only cancers. So it's not just that. It's really just being able to effectively remove that super imposition of tissue that obscures the findings on the 2-D mammogram.

Q: So some of that comes down to just—Is it because every patient is different, that you can potentially miss a really large cancer?

[00:42:11]
A: Yes. Some cancers really look like normal breast tissue, but they're just huge. And so the distortion of tissue is just much better appreciated with the tomosynthesis imaging.

Q: And then you talked about dealing with the insurance companies.

[00:42:34]
A: So that was also a first for me, really exciting. It all started with having the equipment available at our institution. We were, as I mentioned, the fifth in the company to have it. So we wanted to advertise that we had it. We had this technology that was finding more cancers for patients. And so we had a bus that had the equipment on it. And it would drive around. And we had—I was staffing the bus one day. It was just in a parking lot across the street from our hospital. And we had invited some of our state Senators and representatives to come in and take a look at it, and so they came.

[00:43:19]
And so I showed them some example cases on this—on this tomo bus that we had. And this was set up very nicely by the manufacturers. They had specific people who deal with the legislation. And so they helped connect me with the Senators and their [00:43:42] efforts was just incredible. So I was able to review the technology with the Senator and with one of the representatives. And they just couldn't believe it. They felt—I mean even to the lay person, you can see how dramatic it is.

[00:44:00]

So they partnered with me and a few other people to put a billboard and require insurance companies to cover it. And so we were successful in that. And it was really – So I went down to Springfield several times to talk about the technology, and how it's important for the residents of Illinois to be able to have access to this. And they would not have access if the insurance companies were not paying for it.

[00:44:31]
Other states across the country were charging patients $50 dollars, or sometimes more, for the technology. And we really didn't want it to be based on whether patients could afford it or not. So it was a huge success. We were one of the first states, really one of the only states in the country that required insurance companies to cover it. I went to Texas to talk to Blue Cross/Blue Shield, because the HDFC, which is the parent company of the Blue Cross/Blue Shield of Illinois, as well as four other states, was based in Texas And so we convinced them. I met with other insurance companies. So we just had lots of success, in terms of reaching out to individual insurance companies, as well as the mandate after working with them to cover it in the State of Illinois.

Q: So speaking of insurance coverage, did the—oh my. The real name of it suddenly escaped me. Did the Affordable Care Act have an impact on any of your work?

[00:45:44]
A: Well, the Affordable Care Act has been beneficial for women, because it requires coverage for mammography in and of itself, at no charge to the patient. So it's not like they come, and if they haven't met the deductible, they have to pay. So it's a free exam. And that's been really critical, because I really think that we get a lot of patients here who otherwise would not normally get a mammogram, because it's covered. And I think it's important for that to continue. So with that, I do think that because tomosynthesis was considered a mammography service, that that helped us in terms of making sure that there would be no cost to the patient.

Q: If you don't mind my asking, before the ACA came along and changed that, what did a mammography cost in, I don't know, the old days?

[00:46:48]

A: You know, I'm not sure I know. Isn't that terrible as a provider? I don't know how much patients got charged. But you know, I would say, if they were a Medicare patient, it probably would be $50 to $100 dollars for an exam. And just patients can't pay that.

Q: Yeah. Have you had any other dealings with the government? Like have you worked directly with the FDA on anything?

[00:47:25]

A: I've gone to Washington. And that was, that helped facilitate the FDA approval. So we had—You know, it started with individual insurance companies. Then it went to the State of Illinois for requiring the insurance companies to cover it. And then to Washington, to help with FDA approval, which came—I'm sorry. I didn't mean FDA approval. I meant Medicare coverage, which came in 2015, I think.

Q: So what do you have to— [simultaneous conversation] What's that?

[00:48:08]

A: I meant CMS instead of FDA. I'm getting my acronyms messed up. So Centers for Medicare and Medicaid Services, CMS.

Q: So I haven't actually talked to anybody, at least that I know of, who's directly dealt with Medicare. What's it like dealing with them as an institution?

[00:48:28]

A: Well, it was really just going to different Senators in Washington, to help support the bill. So it wasn't as if I dealt with Medicare directly. It was getting the Senators and representatives to sign on for a bill to get it required CMS coverage.

Q: So those visits would sort of be like a breakdown demonstrating the efficacy of this technology versus the other?

[00:49:16]
A: Right. So go to Washington, have appointments with different representatives and Senators. And I would sit down and explain my experience with it, show them some images if they wanted to see them. And really express how disparities in women's healthcare would be realized if we did not have universal coverage for it.

Q: I'm having trouble reading my own handwriting.

[00:50:01]
A: That's why I became a doctor. I've got terrible handwriting.

Q: So to keep skipping around a little bit, I have one follow-up question on my first page of notes that we never got to. What is the experience of RSNA like as a participant? Because I've heard it a few times from the vendor side. But never from the side of a professional who's going there.

[00:50:33]
A: Right. So my first RSNA experience was when I was a resident, actually. And that was my first exposure to Chicago, and I really think contributed to our decision to move to Chicago eventually. But I presented an abstract when I was a resident, head really nothing to do with breast imaging. It was ultrasound. And so it's overwhelming, when you come for the first time there. It's the largest medical meeting in the world, I think. There are over 50,000 people that

attend. And it's international. And always the weekend after Thanksgiving into the following week. So it's the Saturday after Thanksgiving to the following Friday.

[00:51:18]
So, if you don't really know what to look for, it can be very overwhelming. But it is a time, and it's really evolved over the years, with my participation and involvement in the society. But when I first went there, you just don't even know what it's all about. It's an opportunity to meet with the vendors. It's an opportunity to meet with your colleagues, and hear sort of the latest and greatest in what's going on in your field. It serves different purposes for different specialties, in radiology, I would say. Breast imaging has a large presence And so there's a lot of information shared.

[00:52:00]
But some other specialties have their own specialty meetings. And so they are less attended by the other specialties. So for example, I don't think interventional radiology spends a ton of time in RSNA. But there's still some representation there. Now, when I attend, it is—I am so involved in the American College of Radiology, and the Society of Breast Imaging. I'm on the commission. So it's really more an opportunity to meet with people. I attend very few sessions. And pretty much the only ones that I'm giving, actually. I try to attend some of the scientific sessions. But oftentimes get pulled away, because we have so many meetings.

[00:52:39]
So it really serves more as an opportunity to meet and talk about accreditation, and the Commission topics. And so it ends up being quite busy from a societal standpoint, I mean like a Society of Breast Imaging, and American College of Radiology. So it's just because people come all together, and we can meet in person. Now, of course, this year is going to be all virtual. So I'm not sure how that is going to work out. But you know, for example, for the research that we did for tomosynthesis, we met at RSNA every year to sort of get together and present what we had so far on the paper, et cetera. So it's really more of a meeting time, less education, unfortunately I would love to be there just to learn. But that's not what it is for me anymore.

Q: Are you a part of any other professional organizations? Like is there anything else within the field that's comparable to RSNA?

[00:53:44]

A: So the Society of Breast Imaging, in which I'm very involved in, I am actually on the planning committee for 2021 meeting. And we met in Savannah this—It's going to be in Savannah next year, I hope. And so I would say it's very much like the RSNA except it's just for breast imaging. That's very well attended. And it may start taking away from the RSNA, and then I think more people will start attending the Society of Breast Imaging meeting than RSNA, in our field anyway.

[00:54:26]

I think the advantage of the RSNA is that if you practice other specialties, you know, breast imaging as well as other specialties, you can go to the one meeting. But if you only do breast imaging, really the Society of Breast Imaging probably is more effective for learning.

Q: And earlier on in the interview you talked about synthetic imaging. Can you explain what that is?

[00:55:02]

A: So basically, it's taking the information from the tomo data set, and generating a 2-D like picture, a digital mammogram-like picture. So it eliminates the need for exposure for the radiation. And the—I've been involved in evaluating the synthetic images way back, when it first came out, where it was very pixelated. And there really, it approximated a true 2-D mammogram. But it wasn't great. But it is slowly but surely evolving over time. And now, the high resolution synthetic imaging is sometimes hard to tell the difference between that and a true 2-D mammogram. So it's really gotten significantly better.

[00:55:46]

The problem is, is it's a huge file size. And so it takes a long time to reconstruct. And there's some delays in the presentation of the imaging, unless you have, you know, very large bandwidth. So it's very taxing on the computers.

Q: Can you ballpark about how big the file size is?

[00:56:10]
A: Five gigabytes for one exam.

Q: Wow. So what are the storage challenges like for that? Because if you've got, you know, a bunch of women getting one exam per year, you're going to eat up space very quickly, I'd imagine.

[00:56:31]
A: Our IT people don't like me. [laughter] But there are really some newer—Now this is getting out of my area of expertise. But the way I understand it, so this is going to be very much in layman's terms, and I'm sure IT people are cringing the way I'm explaining it. But the way I understand it is, with a lot of the current PACS systems, you have to download some of the information. Some of it is stored locally. But there are newer PACS source stations that can stream it, if you will.

[00:57:05]
So the analogy is, a Netflix movie, that's all streamed now. And so as soon as it's—if you say, "I want to purchase this movie," you can see it straightaway. Whereas in the old days, you have to download it onto your local computer before you could actually watch the whole movie. Or if there's a delay, and you'd get to a certain point, and it would pause. And you'd have to wait for more to download. So that's kind of the way it is right now, with the tomosynthesis images and the high resolution synthetic imaging, is that there's a delay, because it's not totally locally on your computer. Whereas, with the newer PACS systems, it's more like streaming, where it's just available. And it's in the cloud. And you can access it sort of instantaneously.

Q: So can you think about what some of the biggest challenges have been to adopting new methods, new tech, new whatever? You know, this can just be across anything.

[00:58:13]

A: Yeah, two major challenges are cost and acceptance of the data. So you have to have the money, just because it's invariably going to be hardware and software investments that need to be made. And so you have to have a hospital that's willing to do that. If you are in a private practice, and you own the equipment, you're unlikely to want to purchase new equipment until it fails, the old equipment, because it's just coming out of your pocket. Whereas if you are more in academic kind of environment, the cost of replacing equipment can be absorbed by a much larger institution. And so therefore, the cost, I think, hurts less, at least for the department's, from the department's perspective. I'm sure the hospital administrators would argue with me on that one. So the cost is huge.

[00:59:13]

And then, the data has to be there. If you can't show that it's better, then people aren't going to want to buy it. So it's very important to get the research out as soon as possible, so that you can show, with whatever the new technology is, that it's going to be better for patients.

Q: So did you ever have any serious moments of doubt about tomo?

[00:59:38]

A: Oh, I was very nervous. I mean, you know, it looks pretty. But are we really actually finding more cancers? Are we really, you know, making statistically significant difference? And now the naysayers are saying, “Well yeah, you're finding more cancers. But are they the cancers that are actually going to kill women? Or are they just cancers that are slow-growing?” So there's still a lot of criticism out there for the technology. I would argue that it's not just the cancer detection, but it's also the decrease in recall, and the cost to the patient in terms of anxiety, and cost to the patient in terms of returning for additional unnecessary imaging. So that in and of itself, in my

opinion, makes it worth it. So say we don't find any more cancers, but we don't have to call as many people back. I think that's—that's dramatic enough, that it's worth the technology.

Q: Right. Is there any good way to differentiate between the cancers that you need to act on, and the ones that are slow-growing?

[01:00:43]

A: Not right now. Hopefully, with the assistance of AI in the future, we'll be able to—be able to be more specific at the time of the imaging. But right now, the gold standard is biopsy. So—And even then, we don't know which cancers necessarily. We can predict which cancers are more aggressive and which ones are less aggressive. But we don't know necessarily, definitively, which cancers are going to be problematic and which ones are not. So we sort of treat them all the same way.

Q: Right. And how much earlier can you find cancer now?

[01:01:23]

A: I don't know if we've really articulated in terms of earlier. I think it's going to take 20-30 years for us to be able to figure out, you know, whether we're actually saving lives, if you will. But we are definitely finding more invasive cancers, which are the ones that potentially are more life-threatening.

Q: All right. So we've been talking a lot about the imaging. Have there been corresponding changes in cancer treatment?

[01:02:02]

A: I think there's always—there are always improvements in cancer treatment. And not only with improved chemotherapies, and radiation techniques, but also being less aggressive when it's not as necessary So the idea is to be as least toxic to the patient with the greatest benefit. But I still think that there's a long way to go. There are some estimates that the improvments with

mammography contributes to about 50 percent of the lives saved and the therapy contributes another 50 percent. So we're about equal in terms of our contributions for mortality reduction, based on modeling. I mean of course we can't really say for sure. But that's based on data.

Q: So did you ever have the moment where, when you were still learning about tomo and developing that, did you ever have a moment where things just sort of clicked, and you had like this "aha" moment of, like, "Wow. This is such a major improvement." Like if you ever had a moment like that, could you sort of like describe the circumstances around coming to that realization?

[01:03:33]

A: Well, I think, certainly with our paper—So we published a paper in JAMA, the *Journal of American Medical Association,* which is really one of the preeminent journals in the world. And our data really supported some of the early studies coming out of Europe. And the difference was, is that ours was huge. We had, really, half a million patients' data. So it wasn't prospective, but we went back and looked at our early experience. And it was the largest study of its kind, still to this day, I think.

[01:04:11]

And so when we got those results, it was actually at the RSNA when we saw those results. It was very exciting, because we realized that this really was statistically significant. And it had to be, of a study of this size, to show the statistical significance. And that's really what we wanted to show. So it was at that moment. And, as soon as it was published, I got interviewed by so many people. As one of my friends said it, I thought the best was—I was above the fold on the *New York Times* on the front page. So you know you've arrived when you're above the fold. And it wasn't something bad. So that was exciting, being on NPR, and Science Friday, and all kinds of really fun experiences in talking about the results of our research. That was a time of my life I'll never forget.

[01:05:08]

And then subsequently, just because being first author on such a landmark paper, I've been involved in so many other projects. And each time you see these moments where you think, "Wow, this is really making a difference in people's lives." And that just in and of itself is exciting. I would say along the way, I mean we're learning all kinds of—You know, they're just little moments where you understand, after the experience of the technology, spending so much time teaching it, and people sending you cases and saying, "How come this doesn't make sense?" And then, sitting down and trying to figure it out. And you go, "Oh. Now I know why it makes sense." It's just, it's really just spending the time with it. And each bit along the way, you learn something new.

[01:05:56]
So I'm not sure. I mean I would say the biggest moment was when we got—internally, we got the results of our paper, that we knew that this was going to be big. It's just, I think because I see so—Everyone shows me the hard cases, because I'm the local expert, or national expert, I should say. You see all the hard cases, and you figure it out on the way.

Q: How has having that role of being so strongly identified with that particular procedure sort of impacted you?

[01:06:33]
A: Well, it's exciting. I got to travel to Tokyo, and Austria, and all the places around the world, to share my experience and the results of our paper. So just hearing other people—I mean Japan is so different in terms of the way they screen patients. But to be the expert on this technology, really allowed me to get involved in the societies. And I'm really kind of known as that person. So I wrote the BIRADS, which is our—it's the Breast Imaging Reporting and Data Systems. But it's how we describe findings. It's really our dictionary, if you will, and how we assign different codes to radiology reports. And I was asked to write the tomo part of BIRADS.

[01:07:35]

And I'm currently writing a chapter in a book for teaching residents. It's the tomo chapter. So you know, you worry-- I guess it's kind of like being in a movie, and if you are an actor, and you were funny in a movie, then you get asked to do all these other comedies. But, so I've been asked to do a lot of tomo-related research, and teaching. And I think it really facilitated my involvement in the American College of Radiology, as well as our Societies. So I love that part of it. And I wouldn't trade it.

Q: Is there anything that stands out as sort of the most challenging or most negative aspect of it all?

[01:08:34]

A: I think the most negative part is when the media takes sound bites and distorts it. And I don't know if they're intentionally doing it. But it's somewhat complicated, the technology, although I feel like I've done a pretty good job of distilling it down into basic terms. But when sound bites get out saying things such as, “Tomosynthesis doesn't find any important cancers,” you know, you have to distill it down into a headline. And that headline doesn't necessarily explain the whole picture.

[01:09:10]

I would say in general, not just with tomosynthesis, but the naysayers of screening mammography. So I'll give you an example. The USPSTF, which is the United States Preventive Services Taskforce, is is an organization that gives recommendations on when to screen. You know, that's one component of it. So, for example, with breast imaging, it says that they recommend that women get screened every other year, beginning at age 50. Well, what gets lost—So that's the headline, right.

[01:09:52]

But what gets lost in it, is that they don't recommend against getting screened at 40 every year. It's just that they feel that the risks associated with it, our anxiety and unnecessary imaging. So they agree that, with the American College of Radiology and the NCCN, that the most lives are

saved if you screen every year at 40. But they really recommend that you screen at 50. And that just got completely lost.

[01:10:11]
And so then patients get confused, because they think, “Oh, well I don't have to get a mammogram until I'm 50.” Well actually, no. You should start at 40, every year. So it's frustrating in that sense, that the science can be sometimes confusing and misunderstood. And the people who suffer the most are the patients, because they get confused.

Q: So to counter the most negative aspect, what would you say is the most positive?

[01:10:46]
A: I think just knowing that, you know, coming in every day, and making a difference in people's lives, I mean you just can't trade it. It's a feeling that is so gratifying, that as frustrating and as difficult and challenging our job can be at times, if you just go take a step back and realize that, you know, for example, I went back in our electronic medical record, you can go back to see how many cancers you found in the patients that you read. And since 2018, so over the past year and a half, I have found 60 cancers in patients. And so I potentially have saved 60 lives, which you know, I'm sure there's more because of other—that's just my screening population.

[01:11:41]
But to be able to say that you've done that is really powerful. And I try to explain that to my kids, but I don't think they get it yet. They're still teenagers. So they don't understand, you know, it's not just coming in and rolling up your sleeves and doing the work for the day. You're making a difference in people's lives. And it's just unparalleled.

Q: Yeah. I would imagine that's challenging too, because that's 60 very uncomfortable conversations you've had to have with patients.

[01:12:16]

A: Definitely. And I've had a lot more than that, because I've biopsied a patients that have had cancer. So it's not just the patients who come in for screening, but patients who come in with complaints. And so I've seen a lot more cancers than those 60. Those were—Those 60 patients were totally asymptomatic, just coming in to get their mammogram. But we see all kinds of patients. And I would say disproportionately more here at Northwestern, because we're really a tertiary center. We get a lot of patients who come in with really aggressive cancer. So I have that conversation daily. Well, if not daily, every other day, telling patients they have breast cancer.

[01:12:54]
But that is hard. And I think the hardest part, really, is the, you know, we have the potential to find the cancer. But we also can miss cancers. And so I certainly don't ever want to cause anyone harm. So that is definitely a level of stress that you've got to make sure that you remain sharp, and not distracted, and paying attention, because you really don't want to miss something that could have been detected. So I would say that's much harder.

[01:13:22]
I actually, I wouldn't say enjoy is the right word. But telling a patient they've got breast cancer, I feel is an opportunity for me to make it as least painful as possible. And I think I feel—I feel like I can do it better than a lot of other people, who not necessarily in our field, but people who aren't as accustomed to talking to patients. And so it's an opportunity to make the patient feel at ease, and that we will take care of them. And I gravitate towards that, because I feel like I can really make the experience better for that patient.

Q: Okay. So we've talked about professional organizations. Sorry, we're kind of winding down, getting toward the end of my list. Have you been involved in any philanthropy related to your work?

[01:14:35]
A: Certainly, from going to women's organizations. I've spoken at some groups in Chicago that want to hear about breast cancer and the mammography, and trying to educate them on why it's

important to get screened every year at 40, rather than every other year at 50. So I would say a lot of local organizations, I'm involved in a lot, go do a lot of outreach. So I would say primarily outreach. And I think that's very effective, to allow people to have access to an expert in the field. That's really very reassuring for them.

Q: And then, what moments or parts of your career are you most proud of? Is there anything that you would actually do differently if given the chance?

[01:15:37]

A: So I would say I'm most proud of was just publishing our paper on tomosynthesis, which is really groundbreaking, and was the impetus for a lot of change in our field. So that was, as I mentioned, unparalleled. And I don't think I'll ever recreate it. It was amazing. Things that I would do differently? I don't know. I've had a pretty good run. You know, I was in private practice in the beginning of my career, which is unconventional. Usually, people go from academic to private practice, and not the other way around. And I think it was because I got so involved in research, that it really made me realize how much I like the teaching and the research part of it.

[01:16:26]

But I really benefited significantly from having that private practice background, because I understand the business of radiology as well. So it definitely started me later on in the pathway of academics. So I'm still an associate professor instead of full professor at this point. In my career, which I think most people my age, had they been in academics for this long, they probably would have been a full professor. But as I said, I learned a lot along the way. So I don't think I would trade that.

Q: So is there anything throughout our conversation that I haven't asked you, that you really wish I would have?

[01:17:16]

A: Well, I think tomosynthesis, you know, I've been talking about all of its benefits and how great it is. But it's certainly not the be-all-end-all. And I think that gets lost a lot when I do talk about it, because I am so enthusiastic about it. I think it is a better mammogram. But mammography is still very imperfect. And it is limited. And I think tomosynthesis is great for now. But I do think that other technologies, such as AI, and then specifically also breast MRI, is going to be the future.

[01:17:57]
So I don't think that this is going to be necessarily long-term. MRI really has shown dramatic improvements in cancer detection. And my belief is that that's going to be the standard of care going forward in the not-too-distant future. So I'm not sure tomosynthesis is going to be around forever.

Q: What are some of the drawbacks?

[01:18:26]
A: Of MRI? The drawbacks of breast MRI? Or are you talking about tomosynthesis?

Q: Either/or, really.

[01:18:38]
A: So breast MRI is totally different way of imaging the patient. There's no radiation, but there is a contrast injection. And there are some significant problems with placing an IV in everybody. Not everybody can tolerate the contrast. It's a long imaging test, although we've shortened the time. So that's hopefully going to significantly improve. People are claustrophobic. So it's historically not been a great screening tool. But we are slowly but surely improving on the drawbacks of breast MRI, such that I think it will become the next imaging screening test.

Q: Interesting. Are there any other thoughts you'd like to share?

[01:19:33]

A: I think that's it.

Q: Okay. Well, I can't think of anything else. So I always think of some extra follow-up the second we're done with the call.

A: When you hang up. That's okay. You know how to find me.

Q: So I'll go ahead and stop the recording for now. And thank you so much for—oh, where'd the Zoom window go? Thank you so much for speaking with me today.

A: Yeah, thanks for asking all--

END OF INTERVIEW