Better, Safer, Painless, Accurate: Introducing QT Imaging Transcript

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Introduction and Guest Background

Hi. It's Dr. Jenn. Welcome back. I couldn't be more delighted with our next guest and what you are going to be able to take away from it, because of what he is doing and what he's done again and again and again is earth shattering, life changing, disruptive to the nth degree?

This is Dr. John Klock. He got his MD. from Tulane. He is board certified in internal medicine and he is an academic medical oncologist involved in the startup of many disruptive medical equipment companies.

His passion is women's health, children's health. And he's going to tell the story way better than I will. So, Dr. Klock, welcome. I'm so delighted to have you here.

Thank you. It's wonderful to be here. Yeah. Can you start by giving people a little bit of your background because people may see you and see your name and think that they don't know you, but they know you because you've invented some very, really important things.

Well, I, I do pride myself on, you know, being below the radar. And a lot of these things that I'm going to be saying. But I am a medical oncologist, academically trained, and I left the university because I felt that with what was happening in Silicon Valley and I medtech that I would really like to be involved in what's called translation general medicine, where I'm bringing things directly to patients, not just developing some patent on some sort of a gene.

So that's the background. And I chose to work in women's health and childhood health or children's health specifically because there are big needs in this area.

Women and children are not really looked after in the same intensity. They're not. And I think most people don't understand that the vast majority of studies, except for the breast cancer studies, because it doesn't happen frequently enough in men or ovarian cancer.

But the vast majority of studies are done on men. That's correct. So somebody has to step up and and try to deal with it. So that's been my passion for the last 20 or 30 years.

Yeah. So tell us about some of those passion projects that you have brought to this to this world. I was involved in the startup of some of the early medical imaging technologies here in the Bay Area and then also became fascinated with rare diseases.

Womenu2019s Health and Rare Disease Innovation

So I started the first fully dedicated rare disease company called Biomarin Pharmaceuticals. That's probably a familiar name to some people. It's a $19 billion company now.

And, you know, starting companies for diseases that nobody wanted to deal with and where these children were all dying. And these are literally Lazarus treatments.

These children get up out of their wheelchairs and they're blind and they can see they're deaf and they can hear. So this was just really exciting. And now, of course, they're over 100 rare disease companies, one of the fastest growing areas in health care.

So that's one example. The other examples are, of course, what I'm going to talk about, which is that medical imaging has always been a challenge because it's limited by x rays, which are dangerous or other types of radiation.

They're very expensive and they're not really available to healthy people. So that was another area where I saw a huge need. And so that's what I've been working on really for the last.

So tell me what you mean by that. That, that the imaging is not available to healthy people. Can you expand on that a little bit as well? If you're unless you have a really serious medical problem, they cannot justify treating you with radiation, which of course, causes cancer.

I subjecting you to that, plus a heavy metal injection, unless there's really an urgent need. So, for instance, if you have a a pretty healthy baby that suddenly gets sick, you know, they can't just put that baby in a CT scanner or an MRI scanner.

So and a lot of people are concerned about this technology. It's 50 years old, x rays, 100 years old. So really nothing has changed much. It's certainly gotten more expensive to get medical imaging.

It's the number one cost of health care expenses in our country. So it was about time for somebody to develop something new and. Know especially, you know, we are using mammogram for screening for breast cancer.

And the mammographic screening program actually started in the 1970s. And at that time we were doing 2D mammogram. And now around 2012, 2014, we started to do 3D mammograms and actually we are exposing winning to more radiation at younger ages in our screening program.

And the only other thing that we really had for screening was MRI. Well, don't forget, minority women like African-American women, they get breast cancer younger.

It's more aggressive. And, you know, you can't get your mammogram until you're 40 or in some cases, 45 in Europe. So we're missing the whole population of women that need screening, that cannot get it.

And how about how well is mammogram really doing in that younger population anyway? Because in the premenopausal population, the dense breasted woman is not really well-served by mammogram.

And she. Unfortunately, the studies show that mammograms and digital mammography and even digital breast tumor synthesis are still not solving the problem of dense breast imaging, which is half of women.

Yeah. So you're correct. This is an underserved population. Our company received breakthrough device designation by the FDA from the FDA to specifically get this approved for younger women and especially women with high risk.

Yeah, and I do want to be clear that I am not talking about dense breasted women as a result of some kind of disease. It is normal to have dense breasts when you are in the premenopausal stage of life, because that is a stage that you are capable of reproduction.

And if you're capable of reproduction, you should have functional breasts. So it's just it's just part and parcel to having functional breast. And there's been a lot of talk recently, especially in the news that having dense breasts is linked to breast cancer.

Limits of Mammography and MRI Screening

But I think in the premenopausal woman, it's just a function of age and stage in life that may be different in a postmenopausal woman. But what do you think of that?

No. I mean, we need to understand the physiology of women's breasts. And certainly women of reproductive age. They need to have breast tissue glands and ducks in their breast ready to make milk for their expected child.

So that's normal when you go through the menopause and the life change course that goes away. So obviously, if you have less breast tissue, you have a lower risk of cancer.

So really the fact that dense breast women have a slight increase in breast cancer is simply because they have more tissue where it can be. Again, the number one cause of breast cancer in our country is obesity.

That's because your fat makes estrogen and estrogen stimulates the breast tissue and so increases your risk for transformation. And so that and smoking and alcohol and the other things really are very, very important.

If you have cancer, breast. So we have proposed one method of screening to dense breasted women or women with a high risk of breast cancer, or women who have breasts that are difficult to image.

We have proposed that it is appropriate to screen them with MRI, but MRI is not a great screening tool. Well, MRI has several challenges. One, of course, is that it's highly sensitive.

I won't argue with that, but it's so sensitive that began Millennium Lights Up a lot of things that are nothing. So the high false positive rate, somewhere between 70 and 90% means that you get your MRI, but then you may have to get additional testing or biopsies for these findings that are really nothing.

Number two, MRI involves a heavy metal injection called gadolinium that causes kidney problems and accumulates in the body, in the brain. And it's not really safe in the long term.

So the third and final thing is that it's very expensive and most breast MRI is not covered either totally or completely by insurance. So they're very high out-of-pocket costs for women.

So even though it is recommended in certain cases, primarily by the American Cancer Society and the radiology societies, it really is not used as much as some of those people would prefer.

So alternatives to it are certainly coming and are here. So I think we do have choices. And you know, access to MRI isn't great either. And it's a very cumbersome test.

Yes, it is. It takes an hour. And, you know, the costs are between three and $10,000 for the the test. They are working on better and faster techniques for women.

But, you know, they're probably not enough MRI machines in the country to do screening if we really had to. Yeah, and that may not be a bad thing because MRI is not an ideal test.

And if I remember correctly, I think you were charged with coming up with something better. Yeah. So we were getting that go. Well, $20 million from the National Cancer Institute specifically asking us to address the problems of a safe alternative to MRI, number one, inexpensive alternative to MRI number two.

And something that was, you know, more accurate than MRI. So we achieved all three of these. And we continue to be supported by the National Institutes of Health in our work.

That's amazing. So so what is what is this device test that you're talking about? Because I think that people really want to know their people are really struggling with what to screen because mammogram over a lifetime isn't safe.

It's not terribly sensitive in the premenopausal population. It's far more sensitive in the postmenopausal population. And then over a woman's life. All of that radiation exposure is not insignificant.

And there's that trauma with having compression. There's also the trauma with just going for the test. There's something anxiety provoking about the tests in itself, partially because I think people have an inherent trust with that, because so many people have gone for a mammogram and been told that they're fine and then the next thing they know, they have a they feel a lump or have a diagnosis of breast cancer.

So mammograms do miss things and then the flipside of it is that going and having MRI's over and over and over again, even for the people that it's possible for, is really it's not it's not great.

So we are primed for a safe and and better alternative. Well, I'll show you a picture what it is. I think this is quite interesting. Can you see that? I can.

Okay. This is a woman who is having her breast scan using this technology. This is a water bath. So her breast is in a nice, warm water bath. This machine goes around in the water and it's using sound.

Sound just about the spoken word. So this is not anything crazy that's going here. This sound and that sound basically generates an image that is 40 times the resolution of MRI.

So the reason that it is 40 times I'll show you in the next slide, but it's a very nice procedure. More than half the women actually fall asleep during this process.

It takes 4 to 8 minutes. And really, I think it's something that in clinical trials has been shown to be, you know, something that is amazing. This is what happens with MRI.

On the left, MRI takes a slice through a woman's breast and you end up with a voxel or three dimensional pixel in that slice or 22 million pixels in each slice of an MRI with the cutest scan, you get that pixel looked at from multiple different locations, so you end up with 36 billion voxel point data points per voxel versus 183,000.

So you get 200,000 times more data with this technology. And, you know, the images are amazing. You can actually see this is an MRI of a lung in a newborn egg.

You can see this black area. They don't even do MRI of the lung because you can't see anything. But if you look at our technology, you can actually see the lung alveoli here.

So it really is a revolutionary new technology, 100% safe. The cost of a breast MRI may be several thousand dollars because of our scan. It's maybe $300.

So it truly is revolutionary. And you end up with, you know, a test that really compares extremely well against mammography in multiple blinded trials, both with full field digital mammography and breast cancer synthesis as better.

So we're really looking forward to, you know, helping women with this new technology. That's that's really amazing. So I just want to bring up some of the touch points there.

There's no compression. No, ma'am. Right. And each side takes about 4 to 8 minutes. So the total study is around 15 minutes. That's correct. And and it's just submerged in a bath.

Right. More people people are lying on their stomachs. Yes. Yeah. And how much radiation do they get as a result of taking this study? Zero zero. So that's really quite different than what we're screening with now.

A Safer Ultrasound-Based Breast Imaging Alternative

What what do the images look like? What is the sensitivity? Can people trust this study? What what does a negative study mean? It's a good point. I will show you what the images look like here.

You can see on the left here, this is the image of a breast done at the University of California showing the breast tissue is the glandular tissue. And pink here, the image of the scan shows identical.

All the anatomy you see here, we can see down to the level of. So just to clarify the image on the left, the pink and purple image, that is actual breast tissue, right?

Yeah. And then the image on the right is is b is the image that you took? That's correct. Yeah, that's pretty amazing. This is the first time we've ever been able to see the cells within the rows.

Okay. This is the holy grail of medical imaging to be able to see micro anatomy. And of course, you've seen this before. This is a picture of the breast duct system in a living woman.

Again, this is the only technology that can do that. It's very important because cancer develops in the breast ducks. And so having healthy breast ducts and being able to image those is extremely important.

Wow. That is truly amazing. So what do you envision is going to happen with this technology? What's happening with it now and what do you envision is going to happen?

Well, we're starting to place systems that primarily in cancer centers. And we do believe since it is approved, FDA approved for dense breast screening today, any woman with dense breast can do this.

So we're doing two things. We believe that to improve women's breast health, two things need to happen. One, we need to embrace newer, safer technology.

And we need to allow the women to have more choice. So we're setting up direct to consumer centers all over the country for women who can walk in, get this done, $300 and they're out of there.

Absolutely. They get beautiful images that if they report there's no radiation, if there any callbacks, they're always free at our center. So I think is, again, women being able to have these choices and have a safe and inexpensive way to screen their dense breast really is revolutionary.

And I think women need to take control and, you know, use the empowerment that they have to really advocate for newer, safer technology here. And so I think it's I think it's going to be exciting.

Obviously, there is a very large mammography industry in our country and most women are recommended for it by their doctor. So really, I think, you know, it's important to note that 20% of women, 6 to 7 million opt out of mammography, either their first mammogram or their subsequent mammogram.

So this is a huge population that's never going to have their mammogram. So we need to have something for these women as well as the younger women at high risk.

You have strong family history. You don't qualify for the mammogram because you can't get your mammogram until you're 40. In this country. Yeah, but even even in that population, that that test is not a very reliable test.

Well, I have to be careful because, you know, there is this community standard, but I have to take all of the tests that we have done and blinded trials and all the tests that we prepared for.

The FDA have shown this is better than mammography. And so without knocking it particularly, I think we just have to wait and see. And I think ultimately, you know, the science will prevail here.

Yeah, well, you don't have to knock it. I can do that. Right? I'm not held to the same standard you are. And I think it is unfair and a little immoral to not really educate women about the dangers and the harms of mammography.

And I know that we have time and time again with the United States Prevention Task Force. And, you know, there have been periods in time where we have come out and spoken about it, but it seems to get brushed right back down under the rug because, you know, that that part of our medical system is very strong.

But I do I do believe that it's time for something better. And I was so delighted to learn about your work and what you were doing. And I do hope that that centers that feature this technology are going to become readily available to women so that they can make the choice so that the 20% of women that are opting out of mammography because it is painful, because it is traumatic, because it it does emit radiation.

And, you know, radiation does cause breast cancer. I mean, we know that we know that from several studies. We know that from the fact that children who have lymphoma and get radiated in in childhood, a large percentage of

them 20 years later, will present with breast cancer because it was in the field.

Right. And so we just we know that radiation over over time does cause damage, does cause cancer. And it's just so wonderful because it never made sense to me that we were using a test to screen for cancer that actually causes cancer.

It's like a little illogical in my brain, but I'm so delighted to know about this technology and to and to have options for people. Now, women who want to have this test done, they don't need a prescription.

Right. They can just go and get the test correct. Is there any insurance coverage? There is insurance coverage for whole breast ultrasound. But in our state, California, where I am, the problem is that most women have, you know, high premiums and high deductibles.

So we we have very, very strong group of women coming and paying $300 for this because, you know, the mammogram is one thing. It may be covered by a screening reimbursement.

But if you come back and 50% of women get called back, those subsequent maybe six or eight or ten mammograms are usually not covered. And that's $1,000.

If you have handheld ultrasound, that's another thousand dollars. If you have, you know, MRI, that's 3 to $10000. And 90% of those callbacks are nothing.

So a lot of women get discouraged about what I call the mammography paradigm, because once your you take that mammogram and you're one of those 15% that you're worried to death about being called back, and then you have to go through.

I think the callback rate is higher than that, though. Well, I have to be careful. Yeah, that's okay. That's okay. But okay, let's call it 15%. But even so, you know, many of those will go and go on and read to a biopsy.

Yes. Right up percentage will lead to a biopsy, 90% of which are usually negative. Right. Right.

Clinical Benefits, Access, and Screening Use Cases

So with that most false positives and when we talk to the FDA face to face, they ask us two things. First of all, reduce the false positives, because that's that's a $7 billion a year business in the US right there and reduce the biopsy rate.

So these are what are called serious adverse events by the FDA and they are as a public health agency, they are committed to reducing these serious adverse events of mammography.

Yeah. And can you just address how your imaging does does reduce false positive and does reduce biopsy rates? Well, one thing is that we can tell from the images that we have whether you have a sister.

So a mammogram can't tell you whether you have a cyst. You have to either have a handheld ultrasound or a biopsy. So already, you know, up to 20% of women have cysts.

So 20% of these women, they go out of our center and they're told that they have a cyst and they don't need to come back. So right away, just the simple, benign things that women have and a lot of women have them.

I would say most younger women do. You know, this is a huge difference to the mammogram. Also, we have done blinded, randomized trials. As I mentioned, these are published in academic radiology.

And they show clearly that, you know, we reduce callbacks. So we have, you know, a device that's clearly shown to do that. And, you know, just a matter of time, I think, before women become aware of it.

And I think I read somewhere and correct me if I'm wrong, but if you have a negative Q study, you don't need another study again for two years. Correct?

Our technology is more accurate. So the interval between, you know, examinations is longer. Because that that is a very reliable indication that there is nothing going on in breast cancer by and large is a very slow growing lesion.

Of course, there are going to be exceptions, but the vast majority of breast cancers develop in a in a pretty slow manner. And so a negative T scan would mean that there is nothing worrisome going on.

It's I think the problem is that the false negative rates for mammography, especially in women with that stress, is very high. When you have a false negative rate this high, you do need to come more frequently so that the demography physician can't really look carefully at your breast every year when you have a more sensitive test, you don't need that much frequent, more frequent examination.

And are these are these scans read by radiologists or is this a high reading mom or how is that happening? Good point. Now they're right now they read by people artificial.

We do use artificial intelligence in our reading paradigm. But the problem with breast is there are hundreds of different things that you can find in a woman's breast.

99% of them are negative, but every woman is different. It's like a fingerprint and so AI is very hard to train here in this way. We are working on it, obviously, but I don't think for mammography we're going to replace the radiologists with AI very soon.

I'm very glad to hear that, actually. I'm glad to hear that we found an area that AI is not going to replace the human experience. Yeah. So that that is delightful.

Well, I'm fascinated by this technology and I really look forward to it having a significant role in early detection and in improving women's health. And I think it has the opportunity to do that because it can it's accessible.

It is something that I think women won't dread. I have so many women that won't go for a mammogram, B, not because of the radiation, because they don't want to be compressed.

You know, they just they just don't want that experience. And so I think this opens up an opportunity to really take charge of your health for women that didn't have that avenue before.

And I share your long term concerns with gadolinium and with MRI, because I in my practice, I'm testing people who haven't had an MRI in years. And I'm finding gadolinium levels that are like 100 times normal are a hundred times what's expected and that gadolinium isn't going anywhere.

And we are told that it's safe. But I don't know that we know that. Well, I would be the last one to justify using a heavy metal injection in a human being.

Yeah. Most heavy metals do have consequences.

Beyond Breast Imaging: Orthopedics and Infant Care

Yeah. Yeah. And so I just want to summarize what we've talked about today that in the dense breasted women and dense breasts are a normal function of being premenopausal and having breasts that are prepared to nourish a, an infant in the dense breasted woman and MRI's are too sensitive, oversensitive, and there's a high false negative rate, an increased number of biopsies.

The gadolinium is is dangerous and accumulates in the body and in the brain. And it's expensive, not accessible to everyone. And you came up with an alternative to MRI, which is more sensitive, more specific, more reliable, less cumbersome, and hopefully it will be more accessible than MRI ever was.

So I thank you so much for being here today and for replacing the Holy Grail of medical imaging. Oh, I do want to talk about besides screening the breasts, are there any other uses for this imaging?

Well, of course. And I can show you that here. Very interesting that you mention that, because I think here it's trying to get back to something here.

We have done orthopedic and infant imaging. And we're just going to show you some pictures here. And I think that, you know, this technology also is runs on 20 volts.

It's on it's on wheels. And so now we have the opportunity to do orthopedics surgery. Sports team imaging on the field of military uses, which are solar powered, can go on ships and planes and deserts and everything else.

So this is a really a revolutionary technology. Plus, there's nothing to really image infants that is safe today. So we believe this will revolutionize not only women's breast imaging, but orthopedic imaging and really having the first 100% safe scanner for healthy people.

So we can start to do prevention in a different way than we're doing today. So that would be my answer. That that is really amazing and I just can't thank you enough for your dedication or the contributions that you've made.

But I'm just I'm astounded by your brilliance, and I'm just so grateful that people like you exist and that you do the work that you do to make this world a better place.

So I thank you so much. Thank you for the opportunity. It's always a pleasure to speak with you. Great. It's Dr. Jenn. Bye for now.