Discover Cryoablation: A Non-Surgical Breast Cancer Treatment Transcript

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Introduction and Breast Cancer Focus

Well, Dr. Dennis Holmes is such an honor and pleasure to be chatting with you today. And we're we're going to touch and eye on a question that a lot of my patients ask about quite frequently.

Thank you. It's a pleasure to be here. So you focused on on breast cancer. And also tell me a little bit about why that direction out of all and I mean, you've done so much research and study and and gone in that direction.

Why there. Well, actually, my my career started with an interest in vascular surgery, a blood vessel surgery. But, while I was in the midst of training, I had several cancer events in my family.

which sort of redirected my focus. I had to discontinue training for a couple of years, at which during which I had the chance to experience the cancer diagnosis from the side, from the point of view of the family, you know, not just from the provider, but from dealing with the challenges and, hopes and, you know, sometimes not so positive outcomes that patients experience when they're dealing with a diagnosis, including the side effects of treatment.

And in this case, when I resumed training after a two year stint away, I realized I needed to refocus, because in the time that I had casual conversations with people about what was going on in my life, I realized that cancer was so much more common than I ever expected, and I never understood.

Even as a physician, I didn't understand how prevalent it was. One of the themes that kept coming up as I talked about my experience was breast cancer.

So many people have been touched personally or had close relatives, and I also began to understand the unique challenges that women had with dealing with a diagnosis of cancer, something that was life threatening but also affected a part of their identity in many cases.

And so it was pretty easy for me when I decided to focus on ecology, to concentrate specifically on breast ecology from the perspective of not just practicing the standard of care, but raising the standard of care and making treatment options better for women who were dealing with the diagnosis.

And so one of the challenges, as always, you know, when, when should you operate, when should you not operate?

How Treatment Decisions Are Made

You know, as, as a surgeon, when when you see a patient, you know, what what are the kind of the parameters in your head that that when you see patient, you see breast tumor.

You know, if it's if it's localized, if it's in the lymph nodes, if it's gone in other locations, certain size, you know, chest wall, I mean, what are what are the things that go through your head in regards to we need to do surgery or we need to shift over to other type of therapies prior to.

Well, as you can imagine, it can be quite complicated when so many factors are need to be considered. But we begin by first sort of a very basic level understanding the extent of disease and understanding the patient.

If I start with sort of the more anatomical approach, you need to understand, you know, how large a tumor is with respect to the volume of the breast if there are lymph nodes involved, if it's something that can be managed with localized therapy like a partial mastectomy or cryoablation, or if it required a mastectomy, and if in addition, if radiotherapy would be needed, or systemic therapy.

All of these things are sort of driven by the tumor anatomy and the tumor biology, which is even more important because it's not just so much the size, but what is its likely behavior.

You have to overlay that on the fact that, you know, patients have a certain risk tolerance, some someone to do everything for something that doesn't require much care, some want to do minimal things for something that might otherwise require a lot of care.

You have to figure out exactly where the patient is and try to marry those two. you know the anatomy with a patient centered approach of trying to offer to her treatment options that were tolerable and acceptable to her.

so it can be a quite a unique sort of personalized approach is not really the cutting. It took a cookie cutter, as you would imagine. And so one of the things that's really very interesting about this, you know, field is, you know, the complexity of, of care, the evolving options, the fact that there are now newer options available to women, but also the fact that, you know, no matter how advanced we can get with treatments, some patients just want the minimal thing or no and no invasive therapy.

And we have to sort of find a way to to to treat that patient in a way that respects her personal perspective about her self care and their self-image, but also that, as best as possible, gives her the best long term survival and best outcomes and best, you know, symptom management.

Yeah. And and like you talked about, you know, the breast there's so much identity that comes along with that. And so you know to create as minimal damage while that's still still it at the same time walk on the safe side of the fence, you know, when after the therapy is done, becomes really important.

Yes, I would, I would add and when I began my career, even as a, as a, as a resident, before I made the full commitment to practice, you know, breast ontology, I encountered many women who were simply unwilling to accept the treatments that we were offered, that they were so fearful of the the damage that we would cause with surgery or radiation or chemotherapy that they delayed and delayed and delayed therapies such that often the disease was so advanced that there were really very little other, very little else that we could offer except these very, you know, figuring, you know, morbid treatments.

And so it became clear to me that if I wanted to have an impact on sort of the treatment options and hopefully the outcome of patients and how they approach a cancer diagnosis, we need to expand the options so that we can find and offer to them solutions that were more tolerable but effective.

And so wanted that next step. I mean, because that obviously as you're working with patients and like you mentioning they because of the disfiguring effect and because of not wanting to do surgery, probably to the level that was needed, they then waited and then obviously, like you mentioned, they were then at a place was much harder to treat.

So what what was your solution to that? I mean, what what was your next step? Well, I mean, there are multiple solutions.

Introducing Cryoablation as an Alternative

And they and they all were sort of initiated in different ways that, I mean, that the method of moving forward, this from someone who was, you know, academically trained, was to, at the very least, begin to introduce new concepts in the concept of clinical trials.

And so one of the concerns that I would often hear is a fear of radiation. So one of the trials that I had launched in my first year practice, actually a second year practice, was the use of interrupted radiotherapy, which is a way of giving radiation as a single dose during surgery, therefore eliminating the the burden of time that also required for radiation of the breast.

Also the skin of effects in the breast shape effects that radiation can introduce. so that was a solution for that. And

in my when I was in my first year of practice, I went to a meeting and I heard about the concept of cryoablation, which is at the time a technique that was only used for treating benign tumors.

When I saw it, it was very clear to me that this will be a future treatment of breast cancer. And I want to learn how to do it now, so that when we as a community get to the point of offering patients cryoablation for treatment of breast cancer, I will be well-equipped to lead the way.

And so the very next year, I started to I acquired the system and I started to treat benign tumors, which is important to treat, but not really why I got into it.

I really had my eye on the long view, which is that if I can master treating benign tumors at a time, we sort of get around to accepting treating cancers.

You know, it would be easier. In addition, I also join those clinical trials so I can help to develop the initial experience, proof that the concept works.

That's effective. And also to sort of be a leader in the field, to guide other patients and physicians on how to offer this to their patients. So, so what aspect of cryoablation intrigued you?

I mean, what what how is that different? What what cryoablation for people out there? Well, you know, the concept of breast conservation for breast specialists or even in other specialties is that you have to effectively treat the cancer, but you also have to achieve breast cancer misses preserve the breast and as normal a shape as possible, so that the breast preservation is also achieved with a breast cancer.

Mrs.. And we have, you know, plastic surgical techniques and uncle plastic techniques and a lot of other techniques that I use in that have been developed, to optimize the esthetic outcome while also treating cancer.

Well, there's no better way to optimize the outcome of the breast if you than that, removing tissue and not making a large scar. And so what was most appealing about cryoablation is that it was a procedure that would allow us to treat a cancer efficiently.

I believe the cancer ablated margin around the cancer, just as we would do if we were to remove the tissue with lumpectomy, but do it through a small incision during the way that has minimal side effects.

Relatively painless in the office can be done in the office. Patient go home. So it really achieves all of the the the goals of low impact, physically low impact, anatomically low impact in terms of the patient's quality of life and in the end we have an effect to be treated cancer while also having something that has, you know, that preserves her breast appearance.

So how does how does it work? I mean, but know so yeah. Do the patients just just come there's a little procedure. You know, you just kind of freeze the little spot or I mean, what what is a look like?

Everyone who is undergoing a needle biopsy to diagnose their breast cancer has, has experienced. You know, the main components of the traditional procedure.

We you know, we visualize a tumor, we generally perform it. And the ultrasound guidance, we visualize a tumor by ultrasound. Once we've confirmed the location, the size dimension, the most appropriate approach within the nest.

And we then clean the skin with the prep anesthetized and the plan the needle tract and scan and then insert a needle like probe through the center of the mass and freeze it.

There's we use typically liquid nitrogen in office. Although there are other things that can be used. It frees it up to a very cold temperature that creates an ice ball with the tumor sort of sitting in the ice bowl, like the egg sits in the middle of the of like the yolk sits in the middle of an egg.

And we basically freeze about an egg size volume of tissue with the intent of freezing it cold enough so that the center of the ice bowl is ablated. That means that it's colder than -20.

That's the temperature that we need to achieve in order to oblate mammalian tissues. Well, once the freezing starts, we typically continue it for about ten minutes.

We leave the probe in and allow it to thaw passively for about ten minutes more. And then we typically do a second freeze of about ten minutes. So about a three minute period of treatment, once the second freeze is completed, the probe actively warms and heats up.

And that allows us to draw it, withdraw it from the ice Bowl and from the breast. And then the patient, you know, the skin is prepped, a bandage is applied, and the patient can can drive herself home is it's an outpatient procedure done fully under local anesthetic.

It's very similar to having a needle biopsy performed for diagnosis. It's just that we're inserting a needle but a needle for treatment, as opposed to a needle for removal of tissue.

And and what I mean, what are some of the comments that patients are saying when they're going through this in regards to pain, discomfort, you know what what what do they say?

Well, almost universally, they say that the experience is better than the original needle biopsy. Now, partly is that they're they're more emotionally prepared for this.

But we also use a lot more local anesthetic.

How the Cryoablation Procedure Works

freezing is or cooling is pain relieving, which is why we put an ice back on, on a, on a slower surface. So it is less painful in that way. But they also are usually, you know, we spend the time talking about other things.

So, you know, there's a lot of time freezing and waiting and then freezing. It's although I'm actively supporting the process, we're able to engage the patient.

And often we just, you know, talk about their, their life or the things that kind of take them out of the experience. If they if they want to engage. So but the point is that it's a painless procedure.

Once we've injected the little one instead, it, and the freezing itself promotes that, that pain free approach. the main complaint that patients have is that sometimes you have to have them positioned in the not so comfortable position, maybe on their side or with their arm or with the head.

And so we try to keep them comfortable and, and lower their arm as quickly as we can so that, you know, we can keep them in the most comfortable position possible.

And so, so this freezing, then obviously it's cold enough them to kill the cells right? Yes. The goal is to kill the cancer cells, but also kill a margin of normal tissue around it.

Whenever we see a tumor, you know, we can make an estimate of its size. It's one centimeter, but microscopically it might be 1.2, 1.3 1.4cm. So we have to anticipate that the cancer might be slightly larger than it's shown by imaging.

It's the same approach that we use for surgery. We aim for the tumor, but we include a surrounding margin. And so with correlation we aim for the tumor to freeze the part that we can see, but also to freeze a margin around it to compensate for the fact that the tumor might be slightly larger than what we see.

And are, then any kind of limitations, depending on size of, of the tumor that, you know, if you're beyond two

centimeters, you can't or three or what or what, what are the limitations?

Well, there are some general rules that, that we, sort of advise. we follow, particularly sort of as you begin your career offering patients probation, certainly with experience, the rules can change or we can set new rules.

But, you know, the the technology is optimized, is designed for treating tumors that are two centimeters or less that an area a tumor that's that size 20 is a smaller can be treated with a single ablation.

So a single free cycle or freeze thaw freeze with one probe inserted at one time. You can treat a two similar tumor quite well with a margin if it meets that dimension.

And so most of the guidelines that recommend cryo ablation state that it's appropriate for tumors that are less than two centimeters. However, we know from probation when used for treating liver tumors and kidney tumors and other types of tumors that you can perform multiple ablations to treat something that's larger than two centimeters, meaning that you're sort of overlapping a base ablation, like like like Olympic rings, you kind of overlap the rings to cover a larger area.

So I won't say there's no maximum limit. But, you know, with experience, we've developed the ability to treat tumors more than two some years. And in fact, probably most of the tumors that we treat are over two centimeters.

but you know, this the size that's been looked at in most clinical trials or tumors and then just centimeters, and in fact, we're conducting have conducted and are conducting a new clinical trial that limits it to two centimeters or less, because that's really kind of the the tumor that's likely to be most widely accepted.

As for the medical community and for insurance coverage and so forth, as the ones that are appropriate for ablation, Are there people that you say that you are just not a candidate for cryo ablation?

I mean, is, is does that kind of a group exist? It does exist. I mean, I, I see, I mean, I mean, I think for most people that perform this, that group is really large because there will only treat the kind of the low hanging fruit, many of those patients come to me because they do not have access to ablation.

And, you know, I can partly be thankful for them to helping me grow my experience and expertise at treating larger tumors. But there are still some tumors that are just kind of not reasonable to treat backwardation.

we develop ways to still treat many of them, but basically the larger it is, the more ablation, but it becomes a little bit of an unreasonable to treat someone with so many ablations that you're treating the whole breast.

For example, one of the challenges the classic is Shannon's challenge is that if the tumor extends to the skin, then correlation can be offered because it should be some skin distance that's maintained.

That's certainly a rule, but we've developed some techniques to allow skin removal at the at the time of ablation. For people that have limited skin involvement, the major challenge is not so much can you bleed enough volume?

Because often we can bleed enough volume to get around the tumor. The challenge is that patients with large tumors often have a greater burden of disease.

The disease is not just limited to the breast, they also have axillary disease, or they might have a concern or high risk of having systemic disease. And so focusing only on the breast tumor and not addressing the lymph nodes can be problematic for those patients.

For some, we will offer ablation of NF in order to if there's if there's limit it, there's not involvement with the expectation that they will also receive radiation to the rest of nodes.

That's that's a way of kind of treating the nodes without thinking of burden of surgery. But you know, there's a limit and there will be people who, you know, despite having a high burden of disease in the breast, in the nodes, they

may still not want to have surgery or still might want to have radiation in and, or systemic therapy.

And that's really a challenge, you know, that we have to solve in other ways. But crab ablation isn't really the appropriate way to solve those challenges.

Recovery, Healing, and Follow-Up

And you brought up radiation because frequently, I mean, you do the surgery and then you do radiation in an area around that, you know, to, because there's a lot that you can see that that may be there.

I mean, you do kind of the initial border and then radiation around that. So that does that. is that true also with the ablation that you would do the ablation and then followed by radiation, preferably.

So generally speaking, the answer is yes. I mean, the easiest way to think about correlation it's that it's a substitute for surgery, lumpectomy. But all the other rules apply.

If there's an indication for radiation then radiation should still be offered. If there's an indication for. So let's no biopsy. It should still be for if there's an indication on chemotherapy, it just will be offered. It's simply a replacement for lumpectomy.

However, there is a lot of, you know, evolution in how we approach a patient with lumpectomy today. It used to be that every patient who had lumpectomy required radiotherapy.

But now there are a lot of patients who don't require radiotherapy because of the tumor characteristics or the tumor size. And so, you know, for women over the age of 70, many of them with a with the tumor two centimeters or less, the physicians that are positive, most need radiation therapy.

So if they come to us for probation, we offer them probation. But we don't recommend radiation therapy. That age is actually coming down as more and more studies look at subsets of patients who can be managed lumpectomy alone without radiotherapy.

The same is true for lymph node biopsy. It used to be the case that every patient with the cancer diagnosis invasive cancer diagnosis needed unless no biopsy, there are large groups of women.

In fact, there's a recently published study called The Sound Trial, which says that any woman with the tumor two centimeters as long as a tumor meet certain criteria in terms of and her lymph nodes look negative.

The tumor is only two centimeters or less. And then those women don't need to have lymph node surgery. Now, many people haven't adopted this sort of new sort of innovation in terms of how the lymph nodes are managed.

But the point is that my approach is that if if the rules, the rules that apply from lumpectomy. And surgery to be followed by radiotherapy are the same rules that that would apply to probation.

If there are subgroups that do not benefit from this, no biopsy or do not benefit from radiotherapy, then for the probation patients, I will not recommend to them radiation unless no biopsy.

On the other hand, if there are groups that clearly benefit from radiotherapy, also biopsy, I will offer that to patients. I say I will offer that to patients.

Some patients simply say I'm not willing to do it. And then we kind of find a way to sort of engage them, in care so that we can deal with the cancer, which is kind of the real problem, that one that is present, and then find a different way to manage the risk of something potentially developing in the future.

I think that's probably the most pragmatic way of proceeding with that. And so with the lymph nodes, I mean, because a lot of times you see that, I mean, this one looks suspicious, but we were not sure.

I mean, at that time, you know, they, I mean, I, I would assume you recommend that grabbing that lymph node to test it, to see if there are other lymph nodes that's needed.

Right. So what the trials showed, the sound trials showed is that for women with stage one breast cancer, that's two centimeters or less, regardless of the receptor status, the ultrasound shows the lymph nodes to be normal appearing.

Then there's no need for lymph node surgery. If the recurrence rate of the lymph nodes, in people that had lymph node surgery compared to those who didn't was the same.

So doing that so that the point is that ultrasound is highly effective at excluding the presence of clinically meaningful nodes disease. on the other hand, if the patients had an abnormal node, the trial recommended that they undergo a finding the aspiration of the node.

And if it were positive, then they would undergo surgery. If it were negative, they still were able to be treated without lymph node surgery. And so these patients that had either clinically negative nodes or mildly suspicious, those that were biopsy proven to be benign by needle biopsy.

They were managed with no lymph node surgery. And they did just as well as those that will manage with length of surgery. So those are the that's that's the policy that I follow.

However, there will be some patients with the positive note, you know. And so the question is what do you do about those patients. So it kind of depends upon the number of nodes involved.

If they have only 1 or 2 lymph nodes involved, the first recommendation would be surgery. But if they're unwilling to have surgery, I think in many cases you can safely oblate those nodes as long as the patient is willing to have radiotherapy after.

The reason that radiotherapy is recommended after is that if you have 1 or 2 positive, if you have have 1 or 2 grossly positive nodes, you likely have more than one microscopically positive nodes.

And so even though we might not remove those nodes with surgery as we do now, we don't necessarily remove all the nodes just because 1 or 2 are positive.

We do feel that there should be some lymph node directed therapy, that the therapy can be radiotherapy, because radiotherapy is is quite effective at managing microscopic nodal disease within almost no risk of edema.

If you're dealing with early stages, these. Yeah. And that's exactly I mean, the concern that a lot of women has obviously have obviously is the lymphedema, you know, managing that for for the rest of their life, you know, in some cases.

So so yeah, that that's, that's that's great. That's great. I would just add that I think we've evolved a lot. I mean, we used to do more and more, extensive the first surgery, I think if any, we're recognizing that we can do less and less, just deal with gross disease and, leave the remaining disease like a to manage radiotherapy, that in the end, we have the same long term survival but a much lower rate of nerve edema.

By combining radiotherapy with more limited surgery, certain, And and and you mentioned kind of no matter what the receptor, you know, whether it's er PR positive, Her2 positive, that that does not play a role in this decision making in regards to what you're talking about.

it's somewhat does, especially when you get into tumors that are stage two and higher, not so much for stage one but two and higher. The reason for that is for triple negative and Her2 positive breast cancer.

You know, the recommendation is for those patients to begin with systemic therapy, first with surgical therapy or in this case, ablation to follow.

Risks, Limits, and When Surgery Is Still Needed

The reason for that is that there are some advantages of giving systemic therapy. First, because you can monitor response if there's residual disease after completion of the initial round of chemotherapy, initial course of chemotherapy, then there might be additional drugs that are off or the regimen might change.

And so giving the leaving a tumor in place and treating to manage a response is beneficial in determining what further systematic approach will be offered.

So that's one reason why we try to we generally recommend systemic systemic therapy first. However, there are many women who you know that would be the recommendation, but still they would say, I'm not willing to have chemotherapy or I'm not willing to have.

And I heard you therapy. And so the question is, you know, sort of managing the patients, you know, in a way that gives her the best long term outcome.

And in those situations, I would start with option, but then encourage her subsequently to engage, even if it isn't in the full panel of chemotherapy.

Some of the therapies like maybe just immunotherapy, but not chemotherapy as a way of managing the systemic disease, certainly turn her away. And having her seek other options is just is an opportunity for the tumor to grow and become a bigger challenge to treat.

And so we certainly spend a lot more time talking about when I counsel patients about probation, I spend a lot more time talking about everything but probation because they have to understand how it fits into the comprehensive care and how, you know, it just replaces one component.

But you know, in the context of patients in the care, you know, I have to be open to their limitations. And sometimes it's that I'm not willing to start with that as a first thing I want to do with this first, and then I'll consider the other.

And to be frank, many times were able to get those reluctant patients to do at least something more than just correlation, so that we can optimize the local control and optimize the systemic control and overall survival.

Yeah. And yeah, and the the question is always when you have a therapy and how does it fit into the whole picture, you know, where where do you place it.

So then you need to understand the terrain sort of say same needs and understand the environment that that you're dealing with. So you do you know, you do the cryo ablation.

You know, it seems to me, I mean, to me, it's such a more humane way and, and. Yeah, of, of treating them than surgery. I mean, obviously surgery. Yes. But the kind of the disfiguring aspect, the the healing aspect, the time taken, the downtime, the, embodiment of how you need and I mean, all of these other factors that that come into play, when it seems like with cryo ablation and all of that is very, very minimal.

but then also then recovery, I mean, what does that look like? I mean, what after the cryo ablation, what is that? What can people expect? Yes. But I just want to interject that I am a surgeon.

So I do embrace surgery, especially when it's more appropriate or for people that are open to having surgery as opposed to ablation. There are patients for whom I offer correlation, particularly on clinical trial, who stated that they'd rather have surgery.

And so you know, I offer them a treatment that that meets their risk tolerance. and I think I have excellent surgical outcomes, but that's it. I can't I can't have a better outcome than having no incision and those alteration of the same shape of the breast.

And so on is what achieves that. And there's also some advantages with recovery, I mean, which advise patients, for the period after recovery to wear a sports bra or not feeling bra for the first two weeks, typically.

But apart from that, they can return to normal activities the next day. We just asked them to restrict sports so no upper body sports activity for the first two weeks.

But everything else that they did before they can resume, and as long as they wear the bra. And the main reason for wearing the bra is that there's usually a moderate amount of swelling.

And for a larger ablation, there's even more swelling. and there's some bruising that happens and usually peaks and troughs within ten days. And so we try to help them manage the swelling, with the use of, the bra.

But with the use of a bra, relatively few patients require narcotic medications. In fact, we generally don't prescribe it. We ask them to take Tylenol, and that works for 90% of patients.

there's no need for antibiotics. There's no anesthesia or side effects of nausea and so forth. So patients are able to return to normal activity and feel normal much more quickly and require ablation than than with surgery.

So so here you have frozen tissue. What happens with that tissue. Does that become necrotic. Does it break down. Does it. Is there a size difference after what.

What happens then. Can I with those that tissue in itself. Right. So that the typical volume that we aim to a bleed around the tumor, for example, is a volume of about four by three by three centimeters.

So about the size of a, a line or a or an overnight, for example. and that's the ablation zone and surrounding that is about a one seemingly area of injury that we that is frozen but not frozen, not cold enough to kill.

So at the end it's about the size of a medium egg. That is what we we get. That's the thing that you feel after completion of the ablation. Now over a period of about two months, that outer rim, that outer ablation injured area of injury tends to dissolve or is absorbed or, and, and so over that period of time you feel some shrinkage.

And then that's the most dramatic shrinkage. And then the remaining area, the area that's fully ablated, goes away over the course of several years. It largely depends upon the density of the breast tissue and other patient specific factors that determines how rapidly it goes.

But I tend to sell patients to expect it to last for multiple years. for some that might be two years. For some, there might be four years for some may have it may have a permanent scar.

But frankly, what happens is it gradually shrinks down to some minimum volume. And either they won't be able to feel it, or they have a small, palpable scar that remains.

If we abate a larger area, obviously, that takes longer to dissolve. and so basically, what's what's happening for the medical providers is that, you know, there's an area of injury that is necrotic.

And then in terms of granulation tissue, in the granulation tissue gradually remodels and shrinks over time, leaving behind either that necrosis, which can be a palpable scar, or fibrosis, which can be a palpable scar.

we generally tell patients that, you know, they should expect to feel it. it would diminish over time. It'll be initially tender to pressure, but generally it doesn't cause an ongoing pain.

Occasionally there will be sort of stabbing pains at the site, which is normal after a needle biopsy or after surgery or after ablation. And we also tell them that, you know, the mass is closer to the skin.

If the tumor is close to the skin, it'll be more obvious the tumor is near the muscle, and it'll be less obvious if you have a large breasts. Obviously it'll high better.

If you have a small breast, it won't hurt as well. So those are some of the factors that determine how long a patient is aware of it. but, you know, we have a policy of recommending that patients undergo a repeat biopsy of the ablation site six months post ablation.

in our trials, it's required. Outside of the trials, it's not required, but we recommend it. Then the less and partly is to reassure the patient that the thing that they might still field is just a healing scar.

And also to educate the radiologist or the providers caring for those patients, that the thing that they might find on exam or on imaging is simply a healing scar.

When we do a biopsy of those, the typical thing that we see is fibrosis, chronic inflammation and fat necrosis. That's what we typically see in the healing scar.

Just is same thing we'd see in the surgical scar. and and that obviously is very reassuring when you get that result. And do women sometimes choose to do any kind of, cosmetic alterations after or. No.

DCIS Cryoablation and Future Directions

You know, I don't I have very few patients, that have opted to have a surgical procedure performed after the procedure. And in fact, I can only think of one, in recent years.

And she had a fairly large area of ablation, performed, and, it actually was, without providing sort of, you know, information that's inappropriate. She presented with stage four disease.

She had a about a five centimeter tumor, in the breast. And fortunately, you know, the systemic therapy that was used, controlled her systemic disease such that she, you know, sort of had a different outlook on on life and her longevity.

She had still this really large mass in the breast that was healing, and, she opted to have that have a mastectomy performed as part of her just sort of, you know, clearing her chest of this life, the thing that caused her such, you know, stress and burden.

and it was interesting. You know, the provider sent me the pathology report from that mastectomy, and it was 7.5cm of ablated tissue, no evidence of of residual cancer left.

So although I'm, you know, it's unfortunate that she had to choose that that was the right decision for her. But it was also great to see that kind of a validation that even though we had this too large to treat tumor, that we treated, you know, with ablation, we were able to do so effectively and with no evidence of reserve disease when when the tissue was analyzed.

But generally speaking, and the other scenario where it might happen is a patient has ablation and then she has a recurrence outside of the correlation zone.

And she hopes to have a mastectomy at that point. And then we get to look at both the new cancer and the old correlation site. Those are the situations that I, that I can recall where someone, you know, kind of required surgery after the ablation procedure.

are there any kind of risks with the ablation where, there. I mean, because here you're you're freezing. So I mean, surgery, then you cut it out. So you, you have your remove all of that tissue, and there's no tissue there to mess with it.

is there any kind of concerns for the CRI ablation or any risks involved in that process? Yes. So the courageous concern, that people have, and that's a gem, is that, you know, we could potentially underestimate the extent of disease.

And so we might not ablate the complete volume. And they could be they can have a recurrence, as a, as a, as a consequence of that. that means that in selecting patients for correlation, you have to sort of have ideally a complete complement of imaging or at least as much as they're willing to have and have high quality imaging that characterizes a lesion.

Well, also to ablate beyond that, just because you you can't rely on image alone to estimate the risk. But, you know, even in the case of lumpectomy, you know, there's a risk that you could have disease beyond the margins that we don't detect.

And that's the source. That's why we give radiation after lumpectomy because of disease that we can't detect. And so the same is true for ablation that, you know, we have to disclose that we don't get to assess the margins.

And so there might be some information that we don't get with the margin that we would get with an impact on me. and as a result, you know, you could have a recurrence, but most patients are willing to accept that risk.

We give it in the context that, you know, this is this is the reality. But it's important to have follow up imaging to look for any disease that might develop beyond the margins.

And of course, we would encourage you to consider radiation and medication if appropriate, because it helps to manage that risk. the truth is, with lumpectomy, when you give it a it's two synonym, a tumor with root and surrounding margins to pathologists.

And when they examine it and the microscope, they look at less than 1% of the total margin surface. So even though it's a margin analysis, they can tell you confidently in that 1% visualize margin, there was no disease.

So we're giving you less than 1% when you do a lumpectomy. And you know it's not as good as when was it. But with both and even when they tell you the margins are clear, you know just as well as you know that that doesn't mean that there's no disease remaining.

And that's why follow up therapy, maybe radiotherapy and follow up imaging are important to screen for microscopic disease that over time might develop.

Yeah. Yeah. Exactly. Yeah. and. Any any questions or anything that I should have asked, you know, information that you feel is important in this discussion for, for women out there, considering this.

yeah. The common questions that you hear, obviously you've, you've yeah, you've faced a lot of women asking, you know, very. So the two and one, has to do with the, the idea of an, a scalpel effect.

I think that some people are drawn to collaboration because they, they've heard and they have some information that there's a potential for cryoablation to induce an immune response, that can prevent recurrence of cancer in other parts of the body, recurrence of that cancer in other parts of the body.

I will concede that there's a fair amount of evidence that does indicate that the scope of, effect can happen after cryoablation. Most of that data is related to cryoablation perform other types of cancers, not breast cancers.

So I try not to oversell that. There is a benefit that you should expect. I think on the flip side, there's no harm there's no idea that in the case of that, there could be harm to immune system from breast cryoablation, but I just kind of have to put out on the record that it's not clear to to what degree that could there's benefit for doing cryoablation from, immune induction perspective.

We know that there is a response. We just don't know if the response is strong enough to be protective, and therefore you can't rely upon cryoablation alone.

You have to still be open to considering. Excuse me. Open to considering antihistamine therapy or chemotherapy if recommended. Because we can't rely right.

Rely upon cryoablation alone to induce that desirable a scope of effect. Yeah. The second thing I'd like to mention is that most of the evidence supporting cryoablation has focused on the treatment of invasive cancers.

These are kind of mass forming cancers. You can see relatively well by ultrasound. And so you can target them well biologist. but what I'm investigating now and in the clinical trial is the use of cryoablation for treatment of ductal carcinoma in situ or stage zero breast cancer, which, as you know, is generally not mass forming.

It often presents as classifications on a mammogram. And so because of the challenges of performing an ultrasound guided treatment for DCIS, it was excluded from all the trials that have been conducted thus far.

but, you know, about 30,000 women in the US are diagnosed with DCIS each year. So we need to also be open to them. And furthermore, we shouldn't be in the business of treating DCIS more aggressively than we treat invasive cancer.

So I was driven to sort of problem solve, you know, this, and so that we can offer cryoablation to women with DCIS. And in fact, we developed a trial called DCIS Cryoablation trial where women with DCIS spanning two centimeters or less, could be offered cryoablation to facilitate that.

We, have, introduced at the site of DCIS an additional marker that's ultrasound visible. We could also do it with the wire, but ideally an ultrasound visible marker can be inserted by the radiologist at the site of DCIS, which gives us a target.

Then forward to that, we can you know that we could the target that we can aim or the the probe to perform cryoablation. And so in this trial we've in road, we have a small pilot study of 30 women that we are conducting.

we plan to expand it to a larger number of women, but we treat it about 16 so far. I think it's 10 or 11 of them have undergone, that six months post ablation biopsy.

And in every case, there was no residual disease at the ablation site. so it sort of proves the principle that we could only target DCIS effectively, but that cryoablation also works for DCIS.

There was some question that maybe it might not work. The same with invasive cancers for DCIS, and that DCIS might not be a good candidate. But we're proving that it does work for DCIS is just a matter of mapping in the Z's.

And so we have several strategies that we're sort of promoting as a ways to sort of visualize DCIS. So it could be adequately targeted with cryoablation.

Yeah. That's beautiful. Well, Dr. Holmes, thank you so much for what you're doing there. I know there are a lot of women out there grateful for for you moving this technology forward and for all the research you're doing.

I know I'm yeah, I pointed many, many women towards cryoablation and, I think that that is, such a wonderful option to have out there and like you mentioned, I mean, does not exclude surgery when that is needed, but it's it's always nice to have options, you know, to so for women that really are afraid of surgery, doesn't want the impact of surgery.

So thank you. It's my privilege to, to to participate in this a special opportunity and to let to use it as a way of expanding awareness and knowledge about cryoablation.

Because I think, just as you say, it is a it is an option that patients should be able to consider. first have to know about it. And unfortunately, the one reason why patients don't avail themselves to it are providers don't allow their patients to.

It is that they're not aware that it exists as an option. But, I appreciate the opportunity to make it known that it is an option for the right situation.

Thank you. Thank you. Have a great day.