

[MUSIC PLAYING]

**MACEY**

Good evening. And thank you all for joining tonight's webinar, A Revolution in

**NELSON:**

Localization. We are pleased to have Dr. Lisa Mullen and Mehran Habibi present tonight.

Dr. Lisa Mullen is the Assistant Professor of Radiology, Division of Breast Imaging at Johns Hopkins University School of Medicine. And Dr. Mehran Habibi is the Assistant Professor of Surgical Oncology, Medical Director, Johns Hopkins Breast Center at Bayview campus.

Throughout this evening's presentation, you'll have the opportunity to submit questions using the button below. Please feel free to ask a question. And we will hold all questions, however, to the very end of the presentation, allowing for an interactive discussion with our faculty.

Additionally, tonight's presentation is going to be archived and will be made available for those that would like to refer back to any of the educational content shared and/or for those that are unable to listen in live. Again, thank you so much. I look forward to tonight's conversation. Dr. Mullen, please take it away.

**LISA MULLEN:**

Oh, thank you so much, Macey. And thank you to everyone who is participating online this evening. I'm going to be talking about preoperative breast localization, a little about the history of localization, why and how we do it, and the pros and cons of wire localization. Then I'm going to move into more recent non-wire localization techniques, including the tag LOCalizer device from Hologic.

OK. Let's go ahead and get started. So the topic tonight is A Revolution in Localization. So why do we need breast localization? Usually we need to localize for excisional biopsy and lumpectomy.

We have small tumors that are found only on screening mammography. We localize for calcifications, for high risk lesions that need to be excised, for cancers treated with neoadjuvant chemotherapy, and also for positive axillary lymph nodes. In the past, we usually didn't do localization for palpable lesions. But I find that sometimes we're even localizing for palpable lesions to ensure that the lesion is completely

excised with surgery.

Just a few words on the history of localization, basically we've had a need for localization ever since we started doing mammography. And it took a while to come up with some ways to adequately localize for the surgeon. In 1966, Gerald Dodd and colleagues described a straight needle approach for localizing lesions. And in the early 1970s, various methods were described involving straight needles with or without injection of dye. In 1979, Hall and Frank described a hookwire, which was useful because it didn't migrate as much as the straight needles.

And then in 1980, Dan Kopans described a modified hookwire device, which basically springs out into the tissue and then is more difficult to retract. So it stayed in place a little better. And that's the type of wire that we use at Hopkins. And we've used it for just about 40 years at this point.

In 1985, Mark Homer devised a different type of device in which there was a retractable curved wire, sort of a j-shaped wire. And that's still used in a lot of institutions as well.

So the steps to a needle localization procedure are basically that the radiologist reviews the images first and then reviews the images with the surgeon or a surgical team. We decide on a modality for localization. Most localizations are performed either with mammography or ultrasound and occasionally with MRI guidance.

We choose a length of needle. We want to choose the length of needle that minimizes the distance from the skin to the lesion. And then we place the device. And we may mark the skin, depending on surgeon preference.

Then we communicate with our surgeon via a diagram, images, and/or a phone call, just to clear up any potential for misunderstanding. The surgeon then goes ahead and excises the targeted tissue. And then we obtain and review a specimen radiograph to make sure that the lesion and the hookwire have been removed. And then we review that specimen radiograph with our surgeon.

So the traditional wire localization technique has a number of advantages. Number one, it's quite inexpensive. It's been used for decades, as I mentioned, almost four decades. So it's well-established.

There's no limit on the number of wires used or the distance between wires. And the wires can be used to bracket or outline larger lesions, extensive calcifications, or satellite lesions. And there's a variety of needle lengths, anywhere from 3 centimeters to 10 centimeters.

There are some negatives, however. And I think those are behind a lot of the revolution that we're seeing in localization. So wires must be placed on the day of surgery and that leads to a real challenge with scheduling and workflow.

And there's a potential for significant delays in surgery start times. There can be complications related to the procedure itself, such as pain, hematoma, or implant rupture. The location of the wire could affect the surgical plan.

There is potential for wire migration, that the wire could actually move from the position where it was placed by the radiologist between the time the patient leaves the radiology suite and arrives at surgery and is positioned for surgery. There could be a significant change in its position. So that's a problem. The wire is pretty thin and can be transected during surgery. And then part of that wire could be retained as a foreign body.

This is an image of the traditional Kopans-style hookwire that most of us know and love. There's a needle with the hookwire attached. And these are some images from our practice, just showing the hookwire in place on the left side of your screen and then a specimen radiograph on the right side of your screen containing a hookwire.

There are a number of non-wire devices that have been developed over the last 20 years. And I wanted to go through those one by one. In 2001, we saw the first potential replacement for wires. And that was radioactive seeds.

In 2014, radar reflectors were reported. And that's known as the SaviSCOUT. In 2016, we saw magnetic seeds come to market. And that's the Magseed. And then in 2017, the radiofrequency identification tags, or RFID tags, and that's the tag LOCALizer system that is now manufactured and marketed by Hologic.

So these non-wire devices have a number of commonalities. And they all use a single use sterilized device, which is placed within the breast. There's a handheld probe, which is used to locate the device. And then there's a reusable console with

real time audio and visual information. While using [INAUDIBLE] cue the surgeon as to where the device is located. And all of them operate on some sort of a send receive technology.

There are some advantages to using non-wire devices. And one of the major ones is that using one of these devices to decouples placement of the device from the day of surgery. And that allows flexible scheduling for radiology. It reduces OR delays which, in turn, saves time and money. And there's more flexibility of surgery scheduling, including placing that patient as the first case of the day, which is really important.

There are also fewer vasovagal events because the patient isn't fasting and can use anti-anxiety medication if they need it. The other major advantage is that there's no wire. So there's no risk of wire migration or transection. And there's no wire outside of the breast.

The surgical approach is not affected by placement of the device. There's less tissue removed, which may result in a better cosmetic outcome. And there's a lot of potential for improved patient experience, their comfort, the scheduling flexibility, less anxiety, and lower chance of a vasovagal event. And these devices can be used in the axilla as well.

Of course, there are some disadvantages. There's always something. Cost is a big one. These devices are all more costly than the wire localization devices. But then part of that may be offset by the decreased cost from not having an OR delay.

The devices must be two centimeters from each other if we're bracketing the lesion or localizing two lesions that are relatively close together. The devices can't be repositioned once they're deployed. And detection in the OR is limited by the depth of the device from the skin.

The first one of these devices to discuss is radioactive seeds. These were the first alternative to wire localization. And as I said before, were introduced in 2001. The size of the device is five millimeters.

It's an iodine 123 labeled, titanium encased seed. And it can either be a loose seed or preloaded into a needle and can be placed up to five days before surgery. The

surgeon uses a gamma probe to detect the seed in the OR.

One of the major hurdles here is that there are many regulatory issues related to using a radioactive seed. And because of those issues, some institutions have chosen not to use them at all. And that was true at Hopkins.

And just to show you what this looks like, on the top of this slide, there's a diagram of a radioactive seed magnified significantly. In the lower left, we see two seeds on a fingertip. And then lower right, we see a specimen radiograph with the seed in place adjacent to a biopsy clip.

The next type of non-wire device is the SaviSCOUT, and that's a radar reflector technology. The reflector device is 12 millimeters in size with two nitinol antennae, an infrared light detector and a transistor switch, all preloaded into a 16-gauge needle. And after placement, the radiologist checks for an audible signal with a console. So you have to have a special console in the radiology department. And it can be used up to six centimeters in depth.

Here are some images of the SaviSCOUT. The console is at the top of your screen with the probe and applicator. There's a magnified view of the reflector at bottom left. And you can see it's sized next to a dime, just for reference. And then at the right side of your screen, there is a specimen radiograph showing the SaviSCOUT device adjacent to a biopsy clip.

Magseed is the next type of non-wire localization device to discuss. And this is small, 5 millimeters by 0.9 millimeters. It's stainless steel and deployed from a needle. The probe that's used in the OR actually produces a magnetic field that magnetizes the iron in the device. And then the seed becomes a magnet and therefore can be detected by the probe.

But the probe unit provides audio and visual feedback for the surgeon. And it can be detected up to 3 to 4 centimeters from the probe. Again, images of the Magseed device, the console on your left, and upper right corner is a magnified view of the seed as well as an image next to the tip of a pencil, just for reference. And then bottom right is a specimen radiograph showing the seed adjacent to a clip.

And just moving on to the Hologic LOCALizer system, this device is 10 by 2

millimeters. It's a ferrite rod wrapped in copper and encased in glass and has an antimigratory polypropylene sheath. Each tag has a unique ID number that can be displayed on the reader device. And that actually makes the tag LOCALizer system unique amongst the non-wire localization devices, because each tag is uniquely identifiable.

In the operating room, the surgeon uses a battery powered reader that admits and RF signal to the tag which then receives, modifies, and re-emits the signal. The re-emitted signal is received by the handheld reader device used in the operating field to determine the distance from the probe to the tag. And the detection range is up to 6 centimeters. And the reader screen shows the distance to the tag, that unique tag ID number, and also admits an audible signal.

This is an image of the tag LOCALizer. So to the left, you have the reader device. And to the far right is the pencil probe. And in the middle of the screen is the actual applicator device with the little tag at the bottom of your screen.

And on this slide, we can see a magnified view of the tag at bottom left, just showing its various components that I've described. And then the applicators come in a variety of different sizes, 5 centimeters, 7 centimeters, and 10 centimeters.

I wanted to tell you a little bit about a QI project that was done at Hopkins in late 2018. I know Dr. Habibi will go into greater detail about this. But this was the first time that we were using the tag LOCALizer at Hopkins.

And in this study, we enrolled 18 patients who had a tag localization instead of a wire localization. And these patients were compared to a group of patients who had had the more traditional wire localization. And in the patients in the QI project, we saw significantly decreased OR delays. There was some feedback from the radiologists that the applicator was bulky, especially for mammogram localizations, but no problem at all for ultrasound vocalizations.

And I think many of us are familiar with this, radiologists performing a traditional wire localization. And as we can see here, we're using the shadow from the needle hub to make sure that we're going straight in to the breast, which becomes very important for accurate localization. And we can see that little shadow from the lightweight hub.

When I move on to the next slide, you see the first image that we take mammographically after our scout view is this image where we have placed the needle in place. And we can see the square white hub of that 20-gauge needle. And we do not see our needle at all, which means that we have gone in exactly straight, as we had intended.

That's a little bit harder to detect with the LOCalizer applicator, because it's rather larger and radiopaque. And you see that on the right side of your screen. So that can be a limitation in using the device.

So based on the feedback from radiologists, some recent system improvements were made. And one was a silicone coating on the needle to help it move more easily through tissue. And then another was the development of something called the S-needle, which is lighter and less bulky and has a radiolucent hub.

This is actually an image of the S-needles that I described. You can see that clear hub. It's smaller and lighter and also a little bit more radiolucent. And here's an image of a phantom with this S-needle in place. And it is a less bulky device.

And I just wanted to run through a few cases with you, just to show you what this looks like in practice. So my first case is a mammographic localization of DCIS. And here we can see the breast compressed in the alphanumeric grid.

On the left side of your screen there is a small biopsy clip that we're localizing. On the right side of the screen, you can see the tag localization applicator in place. And then moving on, we can see the orthogonal view with the needle in place. And then finally, we've placed the tag in place. And you can actually see the little device next to the biopsy clip. And then finally, here's the specimen radiograph, where you can see the biopsy clip and the tag LOCalizer.

The next case is ultrasound localization of an invasive ductal carcinoma. And we started with an ultrasound image showing an irregular hypoechoic mass with irregular margins. Next image shows the needle coming in from the side with the device in place. And then the final image shows you can see that echogenic white line is the device in place within the mass. And then we do a post-localization mammogram, CCNM and lateral views, showing the tag LOCalizer in place near the

biopsy clip on both views, and then a specimen radiograph showing the tag LOCALizer, the biopsy clip, and the mass.

And another case was mammographic localization of atypical ductal hyperplasia. And in this case, on the left side of your screen you can see the patient is in the alphanumeric grid. There's actually three biopsy clips. We were going after the buckle clip.

And the next image to the right shows the tag LOCALizer applicator in place. And then the orthogonal view on your left screen, this was our first orthogonal view actually showing that our needle is a little bit deep. So we made a measurement and retracted the needle.

Since we hadn't done very many of these we wanted to be sure before we deployed. So we were right in the correct place. And then, as we look in the next slide, we can see the device actually in place, in perfect position adjacent to the clip. And then here's this specimen radiograph to the right side of your screen showing the tag localization device and the biopsy clip.

And the next case is an ultrasound localization of invasive ductal carcinoma. And here's the image from the ultrasound showing a hypoechoic mass with irregular margins. And then the second image shows that echogenic white line through the mass. And that is the device within the mass. Then we have the post-biopsy mammogram CC and lateral views, again, showing the device in place adjacent to the biopsy clip. And our specimen radiograph, again, showing the device next to the biopsy clip.

So in summary, the non-wire localization devices are very promising for workflow and reduction of OR delays. And the most significant challenges are cost, a bulky applicator, and difficulty using more than one device for bracket localization. And I have some references here. And I'm happy to pass the presentation over to my colleague Dr. Habibi.

**MEHRAN**

**HABIBI:**

Thank you very much, Dr. Mullen. And hi, colleagues. Thank you so much for joining us this evening.

And we are going to discuss the wireless localization techniques and some other



devices toward the end of the presentation. So as you know, the advancement of mammography and the screening programs have led to early detection of the breast cancers. And most of the tumors that we are dealing with for surgical intervention are now non-palpable.

And also with the new adjuvant chemotherapy advancements, a lot of cases that we are operating on, we don't feel the masses anymore. And throughout the world, around 1.7 million new cases of breast cancers are diagnosed and the treatments with the wire localization is essentially a majority of the cases that we are doing.

So as Dr. Mullen mentioned, as the standard of practice for several decades, there have been wire localization of these lesions. And the problem is that this wire localization have several associated problems. Now the way that we actually do the procedure is that after the wire is inserted in the breast, the patient goes to the operating room.

And we follow the path of the wire. We make an incision and do a lumpectomy following the path of the wire. And we close the patient.

So the problems associated with the wire localization are several. One of them is that these cases have to be done at the morning of surgery. And the patients are usually haven't eaten anything. They are NPOs.

And they go through this procedure completely awake. And we have some percentage of the patients that they go through the vasovagal reaction. And they are usually associated with the delays in starting the operating room. Because usually, the surgery starts around 7:30 in the morning. And by the time that the localization happens, and usually you are starting the case around 9:30 or 10:00 in the morning, associated delays with it.

And there are some cases that the wires essentially are protruding through the breast. They come to the OR with a styrofoam cup on top of it. And there are occasions that the wires can migrate throughout this transport of the patients from the breast imaging to the operating room. And this problem, as I mentioned, associated with the later starts, with the patient anxiety, and vasovagal symptoms in around 15, 20% of the time and with sometimes the suboptimal placements and the migration of the wire throughout the journey from the breast imaging to the

operating room.

So what we did several years ago, we used a business intelligence software called Tableau in order to gather the information for the cases that we did in two years, aggregate of all the lumpectomy cases with wire localization at two of the hospitals at Hopkins enterprise. The total number of cases that we did was around 600 cases with the wire localization and lumpectomies. And when we looked at the percentage of the delays, if you look at the cases that we do, these cases are the first of the day, it was associated with around 91% of the time that OR started late.

The problem was that also this translated into around 74% of the time the entire room, the entire day had delays. And in only two of the hospitals the total number of the delays led into around 23,000 OR [INAUDIBLE] delays, only associated with one single procedure, essentially. Which when you calculate the cost of the OR, somewhere around a minimum, very conservative, around \$30 per minute, it is associated with the significant amount of cost for the system.

So what we did was that we followed the patients throughout the course of their journey, from the time of the registration to when they go to the breast imaging, get the wire localization, get to the nuclear medicine, and get the [INAUDIBLE] and the injections, and then when they come to the OR. And we saw that they were somewhere around three hours' time associated with. What we did was we did a spaghetti chart which essentially follows all the movements of the patients throughout the process as well as the technologist's and the radiologist's movement throughout one single procedure of a lumpectomy.

And you can see the amount of the movement that is happening between the different-- usually these are the different floors of the hospital. In one of our institutions, they're actually two different buildings of the hospital. And these movements associated with the three hour time that it essentially takes for that wire localization to happen. And that's why it took so much time prior to do the surgery and associating delays with this practice.

As Dr. Mullen mentioned, there are several options for doing something beside the wire localizations. One of them that is practiced a lot is an ultrasound guided resection. It means that the surgeon uses ultrasound in order to identify the location

of the mass during the surgery and then follows the mass with the ultrasound during the dissection.

And this is doable when the lesion is large enough that it's visible with the ultrasound. However, in a lot of cases that are calcifications or lesions after chemotherapy have decreased in size. And you cannot really see the mass very well with the ultrasound. It makes it very difficult to do.

Also when you're doing the operation, you always have obviously have all the lights on. And then when you do the ultrasound, you have to just keep going back and forth between turning the lights down, then the lights on. And it makes the flow of the surgery difficult.

The second option is the radioactive seed localization, as Dr. Mullen mentioned. The problem with the seed is that first, it emits radiation for every day that the patient has the seed internally. It essentially is like getting a full mammogram. And it only can be done in three, four days maximum and six, seven days' window. And also, if the seed gets resected during the surgery, and it gets sucked into the suction, then they have to shut down the OR, they have to find the seed and create a lot of regulatory problems and is really not used very often. There are other devices.

So what we did at Hopkins was that for the QI project that we did, we tested all the available technologies. We did Savi, we did the Magseed as well as the Hologic LOCALizer, and the SaviSCOUT that was out. The first case that we did, actually, was with the SaviSCOUT. As you can see, because it was our first case, we did both wire, as well as the device, to just make sure that everything goes OK.

And the second device that we used was the Magseed device. And here you can see the surgery using the Magseed device. The problem with it was that because it uses the magnetic field into this. And most of our surgical devices are stainless steel. Every time that the device gets close to any other surgical device, you have to reset the machine and go back again. That means that you have to either use a titanium device throughout your entire case or use the plastic devices, which may make it difficult to implement.

So you have seen the appearance of the Hologic LOCALizer system. It has the reader that we use during the surgery. It gives you essentially the distance from the

location of the reader and from the clip.

And then there is a pencil probe that we insert it when the incision is made. And we use the pencil probe to guide us. And it is a very ergonomically helpful device to guide us through the resection. Because it's very small and it's very helpful during the doing the surgery. And the needle that you can see here is an original version of it with the newer version easier, kind of, like, to insert as well as it has the radiolucent hub that is easier to work with.

So in the operating room, when the patient is asleep before we do the surgery, I usually try to locate the location of the tag with the device. And here you can see we just look around.

[DEVICE EMITTING HIGH-PITCHED HUM]

And it gives you the distance of the tip of the reader from the tag. That gives you the best location to make an incision. You can design the incision accordingly to either use it right on that spot, or you can just move it a little bit. I usually like to make an incision in that periareolar, in the intra-areolar area and use that in order to get to the lesion.

And once you make an incision, then you can switch to the pencil probe, a very thin probe. [INAUDIBLE] very nicely, and you can target the location of the mass very, very easily with that technique. And there you can see, again, the distance from the pencil probe to the tag. It gives you a little bit of an indication how well-centered your resection is and your tag is compared to the size of your lumpectomy.

And here you can see the resection was nice. The lesion was smack in the middle of it. And it gives you how large of a distance you have from the tag.

So what we did was we did a QI project. We used the technology of the Hologic LOCalizer to decrease the amount of OR delays associated with that. And we went from having around over 90% OR delays to virtually no delays.

They all went in on time. Two patients essentially had just went to the bathroom right before the surgery and associated there's, like, three minutes before their start time. But other than that, everything went very, very well.

And you can see from the spaghetti chart that we had in the past that by decoupling the entire insertion of the clip from the surgery, we made it into a tiger chart. That the patient comes to pre-op registration, goes to the pre-op holding area, and goes straight to the operating room without any delay. And that was a major success in our QI project to show that you can decrease the delay significantly.

So then we did a pros and cons of all the available technologies that are kind of available to us from the time limitation-- at the time that we did it. This was back in 2018. And there were some of the devices had a limited time that you had to do the surgery, within 30 days. But now almost all of them, you can insert them several months even in advance, several weeks in advance. And you can resect the tumor whenever they are ready for going for surgery.

And the only thing that we noticed was that some of the devices, for example, the SaviSCOUT, because it uses the radar technology, it does interfere with the very bright OR lights. And it was giving us some errors. And we had to essentially decrease the OR lights in order to get a good signal.

And that was something that we noticed with the Savi. The Magseed, as I mentioned, had the problem of using the stainless steel devices, which we use all the time, was not possible. And you had to use plastic surgical devices, which did not work very well, and/or titanium, which are significantly more expensive. Then you have to change your entire [INAUDIBLE] practice for that.

The problem, as I mentioned and Dr. Mullen also mentioned, that for the profile of the original needles with the Hologic LOCALizer because that it was a little bit bulky. But it was improved on the second rendition of it.

So the MRI artifact also is something to consider. The SaviSCOUT doesn't have any MRI artifact. The Magseed and Hologic LOCALizer, they both have some MRI artifact.

But practically, these cases, when you are taking them to the operating room, by the time that you're getting there, all the imaging are completed and are done. It means that by the time that you're ready to schedule them for surgery, if the patient needs an MRI, they already have an MRI. And in order to do the localization prior to surgery, it wouldn't play that much of a role in that sense.

So there are a couple of considerations that I think would be interesting to talk about a little. One of them is the bracketing. So I would say at the beginning of the transition to the wireless technology, it's better to choose the cases that are single lesion and are easier to identify with a tag.

The bracketing, I think it takes a little bit of a more learning curve. And once you are comfortable with it, I think you can do the bracketing fine. Especially with the Hologic LOCALizer, that's the only device that has each of the tags have a different identifiers. And you can essentially know which one you're you are getting close to and that would help during the surgery. But at the beginning, it would need a little bit of practice to get comfortable with it.

And the other one is for the patient with the new adjuvant chemotherapy. Again, as of now, all of the devices, they do have an indication that they can stay in the body for several months. And if the decision is made, if the patient already decided to do a partial mastectomy prior to the chemotherapy, you can go ahead and actually insert the clips and then [INAUDIBLE] afterwards. The problem is the cost of the clips are still a little bit prohibitive of being used routinely at the time of the biopsy. And because of that, as of now, it still is used right before the surgery as the tool for the localization of the tumor.

And the other issue is the lymph node localization. So the problem with the lymph node localization is that usually it is done for the cases that you have a node that is positive when you do the biopsy and the patient gets a new adjuvant chemotherapy. And when you are going back to do the surgery, you want to identify the lymph node as well.

And you can do the tag localization in the lymph node as well. And there's no issue with it. Because the localization can be done essentially anywhere.

The problem is obviously the cost of the clip. And in our practice, we use the India ink because it is just cheaper and it's easy to use. And that's what we are currently using.

So in conclusion the wire localization is associated with a lot of delays in surgery. And there are several alternatives with ultrasound guidance, seed, and there are wireless technologies which helps significantly during the resection. So one of the

devices that is available for localization is actually a PERL.

The concept of the PERL is very interesting. It essentially is the wire. But it's a very thin wire that you can do the localization. And you can apply, insert this wire, and the patient can go home with it. And you can do the surgery several days after the wire's inserted.

It's nice because it does give you the tactile feeling during the surgical procedure the way that we are used to, follow the path of the wire. And it's an interesting concept. And also, it doesn't need any capital investment. You don't pay for the device.

The way that it looks, it essentially curves around the mass. And the very thin wire comes out of the skin. And very easily, essentially, you can lay it over the breast, put a tag [INAUDIBLE] on it, and it stays on for several days.

And here, the way that it looks, it looks like a regular wire insertion. It just does that big curve. And then the wire is much thinner than the normal wire that is used during the normal wire localization.

It's a very interesting device. We are testing it at Hopkins currently now. And I think it can be very nicely used in the context of the bracketing and-- the lesion that you really need to do the wire, this can be done painlessly.

So the next device that I want to talk a little bit about is the BIOZORB. And it is not a way of doing the localization. But once the lumpectomy is completed, the BIOZORB is a device, it's a three-dimensional implantable device. And it gets inserted into the cavity of the lumpectomy.

And the radiation oncology will follow this pattern of the spherical, the three-dimensional shape of the BIOZORB to know exactly where the true cavities of the lumpectomy is. And what they can use it for is to target the boost of the radiation into a true lumpectomy cavity. It's very helpful for the radiation oncologist.

And I put a couple of pictures on. Because the radiologist is going to see, if the BIOZORB is inserted, then you're going to see different patterns of the mammography that are not normally seen during the normal mammography or the

clips, the appearance of them are a little bit different. And I just put some of those pictures that we can see the way that the clips are associated with this three-dimensional, implantable device. It's something that can guide the radiation oncologist to focus the beams of radiation for the boost portion of the dose. So that's another view of the BIOZORB. So thank you very much for spending some time with us. And I'll turn it back to [INAUDIBLE] Macey.

**MACEY**

Thank you, Dr. Habibi and Dr. Mullen. That was an incredible conversation and presentation. Thank you so much.

**NELSON:**

What I'd like to do is remind all of our guests that have any questions to please submit them using the button below. And while we're waiting for more questions to come in, let me share a few that have come in during the presentation.

So this would be a question for Dr. Mullen. It's coming from Dr. Mike Mareo. Do you ever place the device using the stereo room?

**LISA MULLEN:**

So I personally don't use the stereo room for localization at all, although I know that some practices do. But we usually use the alphanumeric grid in the mammography suite.

**MACEY**

Thank you. So given the current COVID-19 situation, how does this impact your use of LOCalizer and workflow?

**NELSON:**

**LISA MULLEN:**

If I could take a stab at that one, Macey, I think we all saw Dr. Habibi's spaghetti chart of the patient moving through various different rooms in the radiology facility on the day of surgery, potentially being transported up and down in an elevator and being exposed to other patients and their family members or visitors. I think we are in a position with COVID-19 where we're really trying to keep patients safe and keep them from being exposed to too many people as they're coming through our clinics.

So I think a device like tag LOCalizer could be really helpful in that the patient could be scheduled to have the tag placed at a low risk, outpatient facility with minimal exposure to others. And then on a separate day, come for surgery and just go directly to the pre-op area and never have to leave that surgical suite for their procedure. So I think, even though it does involve two visits, both visits could be orchestrated in a way that keeps the patient maximally safe. And Dr. Habibi may



have some more comments about that.

**MEHRAN HABIBI:** Absolutely. We actually did that for several cases in the last month, that we had the tag inserted in one of the outpatient centers, and we did the surgery in the hospital, minimizing the patient exposure to the different floors. And they went straight to the operating room with no delays. It works very well.

**LISA MULLEN:** Perfect.

**MACEY NELSON:** Thank you both. And Dr. Habibi, this would be a question for you. How do you find the reliability of the signal of LOCALIZER to help guide you to the lesion?

**MEHRAN HABIBI:** Thank you. It's a great question. When the IV is inserted, the mammography picture will be taken. And you know kind of a little bit where it is. But very nicely with the reader, you can scan the breast throughout. And then you can kind of see where the area of the lesion is.

Once you identify the area with the lowest amount of distance--

[HIGH-PITCHED HUM]

--to the lesion, you can actually mark it. Then you know where it is. And you design your location of your incision based on that.

And once the incision is made, then you can switch back to the pencil probe and very fine targeting with the pencil probe. You can follow the resection of it, just keep checking it with the pencil probe to make sure that you have a nice distance from each of the angles of the resection. And once you contain your lumpectomy, you check it again with the pencil probe to make sure that you have a nice [INAUDIBLE] each of the sides.

And then you take a picture with the device to make sure that the clip is in the specimen. It works very well. Because you're following the path of the tag with the pencil probe throughout your resection. It guides your dissection very nicely.

**MACEY NELSON:** Thank you. And Dr. Mullen, who do you feel would benefit most from this technology? Would you say that it's the radiologist, the surgeon, or the patient?

**LISA MULLEN:** Well, I think probably all three, Macey. And in some ways, it can help improve

relationships as well. Because I know the surgeons are not happy with us if the patient is delayed coming to the operating room. So I think separating these procedures really helps.

I mean, I think it can improve the patient experience. They can be made more comfortable. And you can minimize some of those waiting times. I think it's easy for the radiologist to do this procedure and do it in a way that they're not feeling stressed to get the patient to the operating room at a certain time.

And then on the surgeon side, they're able to have their patient without a delay. So that's very nice. And I think overall it can improve the patient's experience.

Not just for the actual procedures themselves, but we think that, like Dr. Habibi was saying, that he can really guide and tailor his resection to the individual patient, which is very nice. It might actually result in a better cosmetic outcome, which ultimately will be very important for a good patient experience. So I think all three can benefit.

**MACEY** Very good. And we have a question from Dr. Hussein. This would be a question for  
**NELSON:** Dr. Mullen. In radiology, how has your experience been with stereotactic placement of the LOCALizer tag?

**LISA MULLEN:** As I mentioned before, I have not used stereotactic for placement of the tag at all. So I can't really speak to that. I don't have experience with it.

**MACEY** Thank you. Dr. Habibi, a request has come in for you to show the PERL wire. Would  
**NELSON:** you mind terribly holding it up and showing what the PERL wire looks like?

**MEHRAN** I mean, you barely can see the wire. It essentially is coming out of my finger. I  
**HABIBI:** mean, you can kind of see a little bit of it. That is very flexible.

And you can just very easily lay it on top of the breast and put a [INAUDIBLE] on it. And the patient come back for the for the surgery several days later.

In the application of it, it's very similar to the same standard wire localization. And when you insert it in, you can see kind of a curve comes out. Then once you pull it, a very thin wire stays over top of the breast. And you can just lay on top of it and put a [INAUDIBLE].

And when you do the surgery, you can kind of follow the trajectory of the wire to do the lumpectomy. Because as surgeons, we are very comfortable using that technique. And it gives you that nice tactile feeling that you do get with the wire localization. You know, for the bracketing, I think it can be done very nicely. For the lesions that are [INAUDIBLE] and difficult to access them with the tag, you can do that as well.

**MACEY** Thank you. And another request has come in for Dr. Mullen. Would you mind terribly  
**NELSON:** showing the original LOCALizer applicator tag compared to the new S-needle tag applicator?

**LISA MULLEN:** Sure. No problem. So this is the original one. I'm going to hold it up sort of in front of my black jacket so that you can see. That's the original.

And then this is the S-needle Let's see if I can turn it so that it shows well. Sorry. I'm getting kind of a mirror image thing, which is why this looks a little awkward. So original and S-- hopefully, that helps.

**MACEY** Yeah, it does. Thank you so much. And we're going to allow just maybe another  
**NELSON:** couple moments to see if any additional questions have come in. Because we are coming to the top of the hour.

And I want to be sure that all of our attendees that have any remaining questions now is your opportunity to ask. We have these two esteemed colleagues on the line. And we'd love to be able to answer any questions. And as I'm saying that, this is a reminder that this webinar is going to be archived and will be made available for future viewing for those of you that would like to share this information with any of your own colleagues or refer back to it at a future date for any of the information that was shared. So I'm going to give another beat just to make sure that there's no additional questions coming in.

I believe we've gone through all of the questions. So let me say thank you, Dr. Mullen. Thank you, Dr. Habibi.

It was incredibly interesting. And we appreciate your time and dedication to bringing this information forward. It has been a real pleasure listening to the both of you.

And for those of our audience members, thank you for taking time out of your evening to join in. And we look forward to seeing you at a future webinar. Thank you so much and good night.

**MEHRAN**

Thank you, Macey.

**HABIBI:**

[MUSIC PLAYING]