

First I would like to thank the Xofter staff for giving me the chance to speak in this symposium. The title of my presentation is, "Treatment Planning for the Axxent Electronic Brachytherapy System." And the, what I'm trying to focus is on the treatment planning from the user's perspective. So, what are the requirements that need to be implemented in the treatment plan to enable to do planning to be used for the treatment? And that would be one of my objective in this presentation and also I will try to speak about what to expect for the treatment plan to look like and we'll make a comparison with the iridium 192 experience. Everybody knows that the objective of the treatment plan is really to obtain a dwell position and a dwell time and that's the main thing in the breast partial radiation treatment. And I would like to focus that we are talking about the 50 kV source [30:49] that will be implemented throughout the whole presentation in here. The Axxent x-ray source is going to emit radiation in all direction isotopically. And therefore, we think about it as if it's a radioactive source. However, the 50 kilovolt source itself was designed to emulate the iridium 192, especially for the accelerated partial breast treatment. And therefore, we apply the same concept for the radium 192 from the experience of the MammoSite, we always normalize; do a 1.0 cm from the surface of the balloon. And thinking about radioactive source, same thing for the Axxent x-ray source, we can implement TG43 concept in order to obtain the dosimetric parameters. And that's what I list in this slide, what we need to obtain is practically the dose rate distribution, radiodose function, angle distribution, anisotropy function, and so on. As an example we see in the slide, we have the air kerma strength, the dose rate constant for the 50 kilovolt – I'm listing here the other energies as you all just for the sake of adding them into the slide, but that 's what we're going to be utilizing. And I would like to focus on the fact that the effective lengths of the source is practically zero, which makes the application of the TG 43 much simpler that way. And this is a typical radiodose function in the logscale, where we notice that the thread line – I'm talking about the 50 kilovolt – data was obtained from the Monte Carlo simulation, MCMP and compared to the measurement data. Also, anisotropy function that is obtained for all the angles and for all depths, these are data obtained from the MCMP, as well, and all these data are practically tabulated and will be used as a dosimetric parameters to implement in the treatment planning system. So whether you have a BrachyVision or the Plato, the same data will be implemented accordingly. Once that is established, then you go to load your customizing file, you will notice that there is a Xofter source in addition to your ordinary source and that's a good plan. So therefore, you can move on and proceed with the normal treatment planning. Usually whether you are using radiographs or a CT scan in your plan, you can implement those, confirm the balloon integrity, be sure the volume of the balloon is cord axis times zero let's say, contorting at catheters at prescription and patient points, add sources, calculate, optimize. Normal procedure. This slide really tells it all about dosimetry. And what we see in this slide is a depth dose curve for both the 50 kilovolt and iridium 192. And in this particular example, we have a 5.0 cm balloon and we normalize to a 1.0 cm depth from the surface of the balloon. And that's how we see that 340 cGy is normalized to a depth of 3.5 cm. We can distinguish in here, two separate features. If I move from that normalization point toward the source, we will see that the 50 kilovolt dose is always higher than that of the iridium. Practically, in this particular example, the surface of the source, of the bend will be right about there. And we notice that the 50 kilovolt is higher and it will proceed to become higher even inside the balloon in this case, however, that is irrelevant to the treatment of the patient because it doesn't have any treatment effect. If we move the other side now, away from the balloon from the normalization point, we see it constantly that the 50 kilovolt goes below the iridium 192. And that has two, that has two advantages, one is for the patient because now you are treating healthy tissue with less dose compared to that of the

iridium and second to the staffing around, as Kathy talked earlier, you need [35:48] of devices like the apron shield to put on the patient and the staffing will be nearby the patient throughout the treatment. So this is really quite plus features. In this slide I'm showing here a single stationary source from the Xofter 50 kilovolt and what I see from the, what I want to talk about the lower left panel in here, this is just a cross-section that is going perpendicular to the axis of the catheter and we see, as we expect, all the isodose lines are round and circular. What we did in this case, as you see in here, I normalized everything to a 1.0 cm depth from the balloon. However, if we look at the other plane that are crossing the catheter, we see that it resembles like an apple shape and it looks like, more or less, circular in all direction except at the proximal end of the balloon, where we see that all isodoses are kind of converged to one point. For this reason, this area, the proximal end of the balloon, will not provide sufficient dose to the required depth of 1.0 cm. And for that reason, we have to use multiple dwell points in the actual situation. If I want to compare a single dwell position with the iridium 192 source, we see it's more like thick and like circular shapes, except there's a bit of dentation on the proximal and distal ends. In the case of iridium 192, you may get away with a single dwell position during the treatment, however, for the Axxent x-ray source, you have to plan with multiple dwell positions. The balloons provided by Xofter are, have various sizes and various shapes. Some spherical and some are ellipsoidal and therefore the planner has to accommodate all this requirement, accordingly. This is an example of a 5 x 6.5 cm ellipsoidal balloon from which we see from the 3D panel that 1.0 cm is being provided throughout the surface of the balloon. This is a multi-dwell point planning. And if I look at now the other isodose line, we see the 100% isodose line here at 1.0 cm, of course, from the balloon and nicely covering the whole shape. I would like to point out the 200% isodose line, which is practically hugging the surface of the balloon in this case. This is a 3D representation of the same plan, where we also see the 200% isodose line. What we see in this case from the proximal end of the balloon, we see the 200% bulging out and this is because it is trying to converge to the 100% to the same point. But, practically what we achieved is a treatment delivery. And, likewise, what we see, we go all the way to 10% isodose line, we'll appreciate the fact that the [39:12] is not too far from the center of the balloon. If I try to compare the same thing with iridium 192 source, so I replace the source now with iridium sources and re-optimize all over again, we see similar trend in this case. A little bit of dentation on the proximal and the distal ends, 100% covering nicely the balloon all over, 3D representation looks more or less the same. What we see in here, if I look at the 400% isodose line, we see that 20% kind of bulging out from the two ends of the balloon just to try to cover for that little bit of dentation in the iridium, because of the manufacturing process. The 10% isodose line is quite larger, I have to zoom out in this, in this slide to be able to accommodate and show where the 10% isodose line is trying to cover. Xofter applicators – this is a list of all the Xofter applicators. What we see here, that I'm going to take an example, is 3.0 to 4.0, the minimum of 3.0 to 4.0 cm spherical applicator has a smallest diameter of 3.8 cm, so I'm missing here all the diameters. The smallest diameter for each of these applicators. In this case, a 3.8 cm, that's the smallest diameter for this applicator, if we look at the surface to target ratio, we find it to be 2.9 for the Xofter, compared to 2.1 for that of the iridium 192. And that ratio goes down when the balloon filling volume increases and this is quite a feature because 2.9 represent actually the worst case scenario when you expect the highest dose to become on the surface of the balloon for this applicator. If we look at to the other side of the table, and this represent the center to the 50% isodose line distance, or depth, and we see constantly that the Xofter distance is about 5.0 to 6.0 mm closer to the balloon than that that of the iridium. This is just an example of the 50% isodose line. If I want to talk about 10% isodose line, I think that we'd appreciate that it's

much, it's much even closer than that of the iridium. So now we have obtained a plan and we need to now transport the dwell location and the dwell time into the treatment unit. To do so, Xofter enables an add-in into an Excel spreadsheet. And this is the worksheet that we see in this icon in here. When you click on it, you will open up a window, from this you have to enter parameters regarding the balloon and the steps. I would like to point here that this version of the software is an older version; there is currently a newer one and you will get the newer one when you get to the treatment time, which looks completely different, but the idea is the same. You have to fill in all the blanks, but it will include, also, the patient's name and demographic information. Once you fill in all this information, a new window will pop up and you start inserting the position and the dwell time for all the locations. There will be a 16-point dwell point that you can insert in steps of half-centimeter each. That means, in total, there will be seven and a half centimeter, quite plenty and enough to plan multi-dwell points for any kind of applicators we have available. So you start inserting dwell time and points and, as you see in this case, you go back and you can save now all the information into a flashcard. Okay? If you look at the file that you have saved, the dwell file, which is practically a text file, you open it up it will list everything required for the treatment – patient's name, which is not, in this case, available because I didn't have the newer version, balloon information, as well as the dwell and time points for each of the points chosen for the treatment. And at the end here, you see the checks on value that will be useful when you move now your flashcard into the treatment controller that you preserved and you want to make sure that all the information saved in this file is preserved and nicely into the treatment unit. So now we proceed that way from the treatment planning system. We implemented all the dosimetric parameter. We moved the information manually to the, to the worksheet and saved information on a flashcard and move it into the controller. So, in summary, what we need to do on every one of us contributing to this clinical trial is to implement TG 43 data that is already obtained on your treatment planning system. And this will be done from the physicist part on your side, as well as from the help of the Xofter staff. And then produce, in a normal fashion, a plan. There is nothing secret about that; everybody's familiar with the MammoSite experience and you will practice practically the same thing, however we have to emphasize that we're talking about multiple-dwell points in this situation. When the plan is finalized, move it to the controller. I would like to end up my talk with the fact that we know from experience that when the surgeon put in the balloon into the patient breast and then stitch it out and leave and fill in the balloon with the solution, often we end up having deformed balloon. Very seldom cases we find balloon that are remaining spherical or ellipsoidal. So the plan that has to come up with some kind of, you know, plan that is, that will make treatment feasible for the physician in this case. So this is just a non-clinical demonstration of you can really be as flexible as you want in producing a plan that way. Thank you so much.