Interventional MRI for DBS Implantation Lecture
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[Slide 1] I appreciate the opportunity to be able talk to everybody and I know we got some old friends here downstairs in San Francisco and we're going to make our way down there after we are all done here and it's nice to make some friends at other sites as well.

So, what I am going to talk about today is a new technique that we are doing for deep brain stimulation surgery and we're very excited about this. We started doing this at UCSF about five years ago now and we're about to start offering this at the San Francisco VA, so we are very very happy about this.

[Slide 2] So, we've been very fortunate to see a lot of technological advances in DBS surgery over the years. We've got very fancy ways of imaging the brain; more and more sophisticated ways of making sure these electrodes get into the right place. And yet, many of the basic principles of deep brain stimulation surgery really haven't changed a lot over the last decade.

For those of you that have heard about DBS, and I am sure there are people in the audience that have had DBS. [Slide 3] It's a very specific procedure. We place a frame on the patient's head. We have the patient awake during a portion of the surgery. We do that because we use brain physiology and a technique called micro-electrode recording to map these various brain areas to make sure we are in the right spot. This requires the patient be awake. It does require that we have to penetrate the brain several times with a small listening electrode before we can put the final deep brain stimulation electrode in place. And so, this may increase the risk of causing bleeding in the brain and it also requires that the patient be awake for part of the procedure. [Slide 4] So, there are some disadvantages to traditional DBS. The patient has to be awake. Many, many patients do very well with DBS surgery, but some have difficulty tolerating this procedure. This process of recording from the brain is very technically demanding. It adds a lot of time to the implantation procedure.

When we do traditional DBS we rely on imaging that's obtained before we get into the operating room. And so, once we get into the operating room and make a little hole in the head some of the spinal fluid comes out, some air gets in, and the brain can shift around a little bit and that can change our targeting very subtlety. And then finally, as good as we have gotten at getting these electrodes into the best possible spot, we are never really absolutely sure that the electrodes are right where we want it to be until we get an MRI scan or a CAT scan after surgery. There is no immediate feedback to make sure there hasn't been any bleeding in the brain or the electrode is in the best possible spot. So, in the mid 1990's, my surgical partner here, Dr. Phil Starr, and I were at different institutions but both were involved in the development of a technique called interventional or intraoperative MRI. This is a way of doing brain surgery inside of an MRI scanner. [Slide 5] And here are a couple of pictures of three different MRI scanners that have been specifically modified to allow surgeons to do surgery inside the scanner and this has predominantly been used historically for brain tumor removal. So, you can get very elegant pictures of the brain and make sure that you have gotten all of the tumor out.

We started to think about how could we apply this to DBS surgery. And so, here is a little cartoon. [Slides 6 and 7] This is a map of the center portion of the brain and the subthalamic nucleus, which is the area that we implant the DBS electrodes, is this green almond shape area on the right of the screen here. [Slide 8] So, if you look at a lot of investigators who have published papers about where's the best possible place in the STN to put a DBS electrode there have been some disagreements, but if you look at this image on the right you will see this color-coded where all these different papers have shown, you know, the best place to put these electrodes, and they all sort of converge, if you'll notice, in the same area of the STN, the subthalamic nucleus.

[Slide 9] So, what we have been doing here for years - over a decade - with our traditional implantations is to put the electrode there where that little grey dot is. It's in the sort of back part of the STN and we aim the stereotactic frame to point at that location. And then, we change the spot a little bit based upon what the MRI scan looks like. So, we start to think about maybe this is an ideal way of applying interventional MRI to DBS surgery. [Slide 10] You can see the STN on an MRI scan. You can see this part of the STN where you want the electrode to be, which is in these little orange spots right here, and we know from our own experience and all these other centers that have published data on this that if you get the electrode in that little orange zone, patients tend to do very very well.

So, we've developed this technique called interventional MRI DBS implantation. [Slide 11] And this is a picture of what it looks like. The entire procedure takes place with the patient inside an MRI scanner. So, if you notice just over my right shoulder there's an MRI scan. It may look a little funny because it is draped in a blue and clear sterile drape. And right over my shoulder you can just barely see the top of the patient's head. And we're getting real-time MRI pictures and the surgeons in the room can look at those TV monitors to the left-hand side of the screen and we can see exactly where we are during the procedure.

Now, the technology that really allowed us to do this was technology that was developed for a technique called frameless DBS. [Slide 12] And this was developed in the early part of this decade and it was based around a little plastic device that aimed on the skull and allowed us to use an optical computer system to track surgical instruments in the operating room. [Slide 13] And we can aim DBS electrodes into the brain using this little skull-mounted plastic aiming device instead of that big bulky metal stereotactic frame. And this is a close up of what that plastic device looks like. So, this actually is not a patient that didn't do well. This is a plastic model of the skull. [Laughter] I'll let all the laughter to die down. And so, you can see it mounts on the top of the patient's head and there is a little stick that comes up. I It's called the fluid stem and that is filled with saline and it turns out that you can see saline very well on MRI scans. It allows us to move and aim this device so that it's pointing at the subthalamic nucleus.

[Slide 14] So, there's no stereotactic frame. However, we do want the patient's head to remain relatively still, so there is this little black head-holder; it looks like a little half moon. And so, the patient lays down in this and it holds the patient's head still.

The first distinction between this technique and the traditional implantation is that there's no stereotactic frame. The second big difference is that the patient does not have to be awake for the surgery. Because we can use MRI to see exactly where we are, we don't need to rely on this brain mapping technique and so, the patients don't have to be awake.

So, we put the patient under general anesthesia. And you can see a patient just getting ready to lay down on the table right in background there. [Slide 15] And once the patient is asleep we put them in the little head-holder and there are these little … we call them coils. They're part of the MRI machine. They look like lollipops. You'll see these two circles on either side of the patient's head and those are what allow us to get the high resolution picture from the patient's brain during the procedure. So, after the patient is all packaged up we put them into the MRI scanner.

[Slide 16] So, this is a patient. We're looking at the top of the head and the patient's lying down in the bore or open part of the doughnut of an MRI scanner and we typically will put two electrodes in at once. And you can see we're holding the sort of bottoms of these skull plastic-mounting aiming devices on either side of the head to make sure that they're not too close to each other, so that they don't bump into each other or interfere with each other. [Slide 17] And this is an actual picture during a real procedure. So, again you can see in the center is the top of the patient's head. All of that plastic stuff is a sterile drape that keeps the environment clean and sterile so we can safely do surgery. And you can see these two plastic aiming devices on top of the patient's head, so this is actually what it looks like from the outside during an actual implantation.

[Slide 18] And this is what the MRI pictures look [like]. So, this is an actual MRI scan and we're picking a place to put the electrode and I know this doesn't project very well and it looks like a bunch of gray stuff. So, I'll help you out here. There's a little part of the brain call the red nucleus, which is that red dot there and just to the right of that is going to be this green almond-shaped area. That's the subthalamic nucleus. [Slide 19] And so, we tell the MRI scanner that's the spot where we want to go and it gives us a little three dimensional coordinate for that spot and then this is simply a matter of aiming the device at that spot.

[Slide 20] So, these are some actual MRI scans during an implantation procedure. So, the patient's … if you look on the left side of the screen here, that's the patient's head. You can see the brain, all that grey stuff in the center of the patient's head, and it looks like there's a stick that is sticking up out of the patient's head. That's that saline-filled stem. That is hooked into that plastic skull-mounted aiming device. The plastic is invisible on MRI so all you can see is the saline filled aiming device there and we just need to manipulate or move that stick so it's in line with that yellow line there and when we have done that we've successfully aimed the device at the brain target.

[Slide 21] And so, to do that we reach into the MRI scanner. We manipulate the device by hand and we look at images that are on these little TV screens inside the MRI scanner room. [Slide 22] This is a picture of what we are actually looking at while we are doing this. So, you will see a diagonal line there in the center of this MRI picture and the center dot of that line is where we want to be, is where we want the device to be aimed. And that little white dot near the bottom of the screen is where that little device is actually aimed and so, we just reach in and we make the little dots line up. And when we do that we're all set. My father told me that playing video games would never pay off, but he was wrong in this instance.

[Slide 23] So, this is what it looks like. Again, some actual pictures from the procedure. So, the top two pictures show that saline-filled aiming stick pointing right where we want it to be and if you look at the bottom two images you'll see a little dark line in the brain about … well, it's about half way down to the subthalamic nucleus. So, these are live pictures during implantation. We can see where the electrode is at any given moment and we can make sure that we're on target all the way down as we lower the electrode down to the STN.

[Slide 24] And finally some pictures again; just MRI pictures. I know these might be a little bit hard to see, but if you look at the top left and top right you'll see sort of a before and after electrode implantation on the right side there. So we have … the important point here is that we can immediately see if we've really got the electrode in the best possible spot and we can also make sure that we haven't had any bleeding or any other complications during the procedure. So, we find it very very useful.

[Slide 25] So, there are a number of advantages. We can really use the full potential of real-time image guidance. We can take into account the fact that the brain does shift around a little bit during these procedures and we can take that into account as we are lowering the electrode down. We can't really do that in the regular operating room. Also, people have variations in their anatomy. Some people have big feet, some people have little feet, and the subthalamic nucleus' varies in size and shape from patient to patient. Something that we think as a big advantage is that we can essentially place these electrodes in the vast majority of patients with just a single penetration in the brain, or what we call a one pass placement. We don't need to do MER, or microelectronic recordings, so we don't have to have the patient awake. And patients generally if they are going to have a brain operation, they prefer to be asleep than awake and we can do that.

We cut the procedure time down by about 50%. So, it takes about half the time of a normal implantation and then finally, we have an immediate detection of any complications that may have occurred.

So, I have some sort of technical sounding slides that I give when I am talking to other doctors about this technique. But, I find that Parkinson's patients are a very sophisticated bunch, so we'll show these to you.

[Slide 26] About a year and half ago, we started looking at the accuracy of this technique and at that point we had put in 53 electrodes in 29 patients. And, 87% of the electrodes we put in, which was all but four of these electrodes, were all placed with a single penetration of the brain and no patient had more than two penetrations to the brain. So, there were four patients that we got part way down or all the way down, didn't like where we were, came back up, adjusted, and then went back down again.

Now, to just give you some perspective, we looked at how many times we penetrated the brain in a traditional implantation and it's about 3.2 times per side of the brain, so we're really cutting our brain penetrations down by about 30%. We looked at the error, the difference between the tip of the electrode where it really ended up and where we wanted it to end up, and it was about 2.2 millimeters. And again to give you some perspective, the diameter of the electrode that we're putting in is about 1.2 millimeters, so this was about the largest average error that we saw was about 1 diameter of electrode away from where we really wanted it, which is very good and very helpful.

[Slide 27] This is just a little busy table, but what we did is we looked to see what's the statistical significance. In other words, we see this accuracy; is it … how does it compare to a regular frame based implantation or these other traditional techniques? And what this table is showing - all the way on the right side of the column - so, our average error was about 2 millimeters in the MR technique. If we look at using a traditional frame, it was about 3 millimeters, And the 3 millimeter error can be as high as about 4.5 millimeters. So, there's a statistically significant improvement in the accuracy of this technique over using a traditional frame.

We also looked at the clinical outcome, so for those of you that have been in a clinical study or sometimes your neurologist will do this, they do something called a UPDRS test. That stands for Unified Parkinson's Disease Rating Scale. And a lot of neurologist will do this, they'll have you come into the office without having taken your medications yet that day and they'll have you do a series of, you know, holding your arms out, have you get up and stand and walk a certain distance, and they will time you. They'll score you on how well you can do these tasks. Then they'll have you take your medications and they'll have to do that again.

And we know how much patients usually improve with regular DBS. We wanted to see how much did they improve with MR DBS. Was it different? And we really wouldn't expect the MR technique to be better than the best implantation using a frame. We would expect them to be equivalent. We're not really putting the electrode in a different place. We're just using a different technique to get it there. [Slide 28] And what this slide shows is that the scores before surgery verses after surgery … the scores are very comparable between the two groups.

Now, early on we did not have a drill that we could use inside the MRI scanner and so, the first ten patients that we did we had to make the opening in the skin and actually create the little hole in the skull in a separate adjacent procedure room and then move the patient into the MRI scanner. [Slide 29] And as you might imagine that, in theory, could increase your risk of infection and indeed in the first ten patients we did have two infections and we actually stopped doing this until we could acquire an MR-compatible drill. So, this is a drill that will work inside the MRI scanner and in the subsequent - we are now up to 70 some patients total, I think we might be up to 80 now - we've had no further infections beyond that first ten patients and in the series we've had no hemorrhages yet. It's had a very, we think, good safety profile.

Now, this little plastic aiming device we have been talking about is called the NexFrame. That's the name of this. And it's been very good to us. It's been a good stable aiming platform for us. [Slide 30] However, it was not designed strictly to do this procedure. It was done to do frameless DBS in a regular operating room. It does have limitations and so, two and a half years ago we were very pleased to be able to partner with a company in Los Angeles, called SurgiVision, and we in collaboration with them have developed something called ClearPoint and this is a completely new fully-integrated system specifically designed to do DBS implantations inside an MRI Scanner. [Slide 31] So, it consists of a skull-mounted aiming device, which you see on the left side of the screen. It's again made of plastic, but it's much narrower. We can put two of them on the top of the head much closer to each other. So, they don't interfere with each other. It has a … If you look at the lower right picture, that's a little cartoon of a patient's head inside an MRI scanner [and] you can see a little remote cable system that comes out to the edge of the opening of the MRI scanner, so we can steer this and aim it remotely, so we don't have to reach into the MRI scanner. And then finally, there's a software environment. So, we've created a software environment that runs on a laptop computer and you take that laptop and you can plug it into a General Electric scanner in San Francisco and do one of these procedures and then you can load that laptop up and you can fly to Hong Kong and you can do the same exact procedure in a Phillips scanner in China, and it looks and feels exactly the same. And so, it allows you to do these procedures essentially on any MRI scanner. So, we're very very excited about ClearPoint.

So, the future, we think, is very bright for DBS in general and we're very excited about this new technique. And we'll look forward to giving you an update in the years to come on how things are going when we start here at the San Francisco VA.

[Slide 32] And I appreciate your time. Thank you.