Sensors and Actuators

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Lecture – 60

MEMS based sensor for catheter contact force measurement

In this module I will be talking about, a very important problem related to heart and that is called atrial fibrillation. Now generally when you see the heart pumps uniformly, that uniform pumping of the heart is because of the synchronized electrical signals. But, in certain cases, the electrical signals start misbehaving, and in that case, either the hearts are pumping very heavily, which we call arrhythmia or it starts pumping unevenly or beating unevenly; that is because the miss firing of signal and that is called atrial fibrillation, alright.

So, if you understand how the heart, we generally learn in biology right that what is the anatomy of the heart. So, just to recall quickly before we move to that problem, we will show you the or I will show you the heart, the schematic of that; and then what is the actual problem, which is atrial fibrillation in a very short video about 3 minutes. And then what are the different ways to cure this particular problem and where are the gaps; that we can fill with the help of designing interesting or innovative sensors. So, that is a complete idea.

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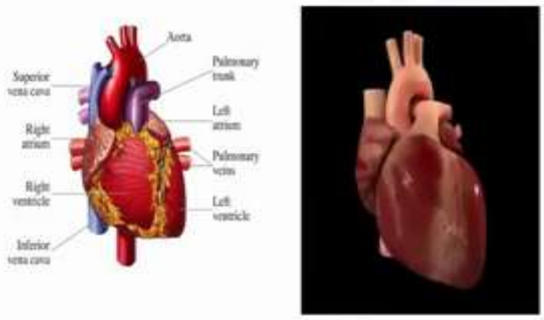

So, if you see the screen, you will see that this is something which is we are being taught from a long time; a heart is an aorta and you cannot we cannot think something else because this is our heart is. We have pulmonary veins, left atrium, right atrium and right ventricle, left ventricle four chambers as you know right. Inferior vena cava, pulmonary trunks, superior vena cava and then, this is just basic things there is a fiber of freeze and a lot of other things which you are not getting into detail.

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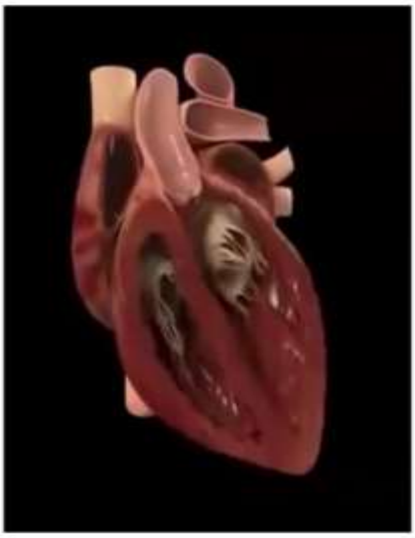

If I play this video just tell how the heartbeats, but we will I will show it to you in detail about that video.

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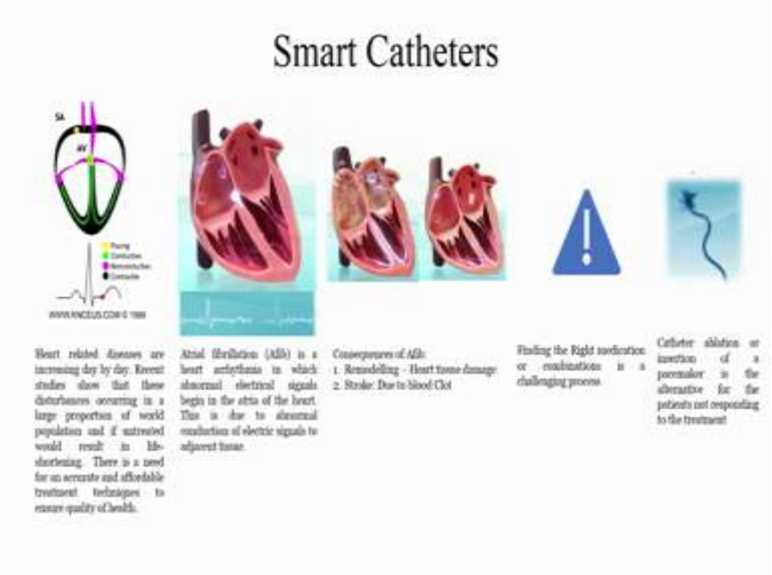

Smart Catheters

Heart related diseases are increasing day by day. Recent studies show that these disturbances occurring in a large proportion of world population and if untreated would result in life-shortening. There is a need for an accurate and affordable treatment techniques to ensure quality of health.

Atrial fibrillation (Afib) is a heart arrhythmia in which abnormal electrical signals begin in the atria of the heart. This is due to abnormal conduction of electric signals to adjacent tissue.

Consequences of Afib:
1. Remodelling - Heart tissue damage
2. Stroke: Due to blood Clot

Finding the Right medication or combinations is a challenging process

Catheter ablation or insertion of a pacemaker is the alternative for the patients not responding to the treatment

So, if you move to the next topic which is the smart catheters, this is what we are interested in a fabricating, smart catheter. Now let me tell you what exactly the catheter means first, and then what is smart means; but before we understand smart catheters or catheter itself, we need to understand what exactly the problem within this particular case.

So, heart diseases are increasing day by day as you know, recent studies say that disturbance occurring in large pollution of the world and if untreated would result in a life-shortening. There is a need for accurate and affordable treatment techniques to ensure health quality right. Now we are talking about AFIB or atrial fibrillation; which is a heart arrhythmia in which abnormal electrical signals begin in the atria of the heart. This is due to abnormal conduction of electrical signals; that you can see here if you see this ECG waveform, then in this through the particular circle you will see there is sudden a heartbeat, there is a QRS wave, right.

So, why there are two very closely spaced ECG signals compared to how it should be like this; this is because of the misfiring of signal, ok. So, like come to how consequences of AFIB or what are the difficulties that may arise, is that remodeling of heart tissue will occur; and then it there can be stroke due to blood clot because of this uneven beating of heart; and that blood clot can go anywhere including the brain and can cause stroke.

So, the way to treat this is mostly with medications; however, the right medications and combination is a very challenging process like any other medication. Screening is a very important problem; how to screen a particular drug and we will be quickly looking at that particular problem as well. And when you talk about treating it, then what happens is; that this surgeon will insert a catheter and will ablate the tissue.

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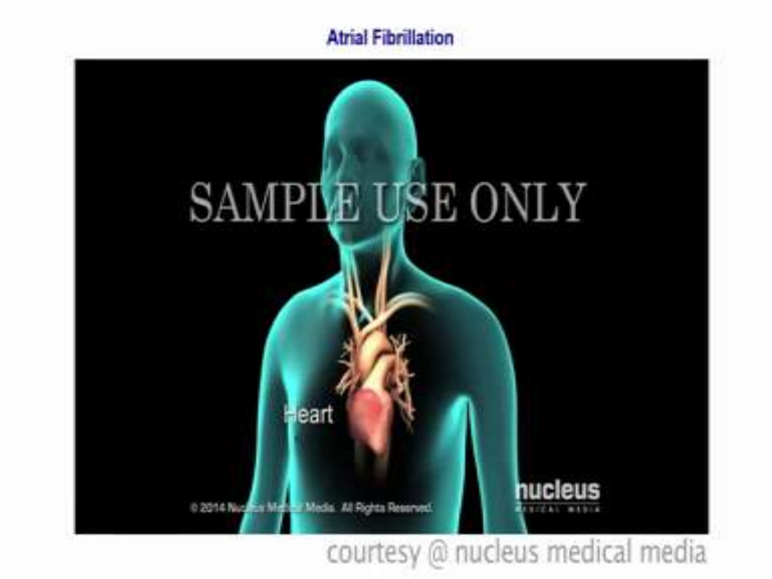

Now, we will talk about this after video, so that whatever I am talking you will get it. So, let me play the video.

Depending on the activity level, the heartbeats about 60 to 100 times per minute, maybe higher during exercise or lower at rest.

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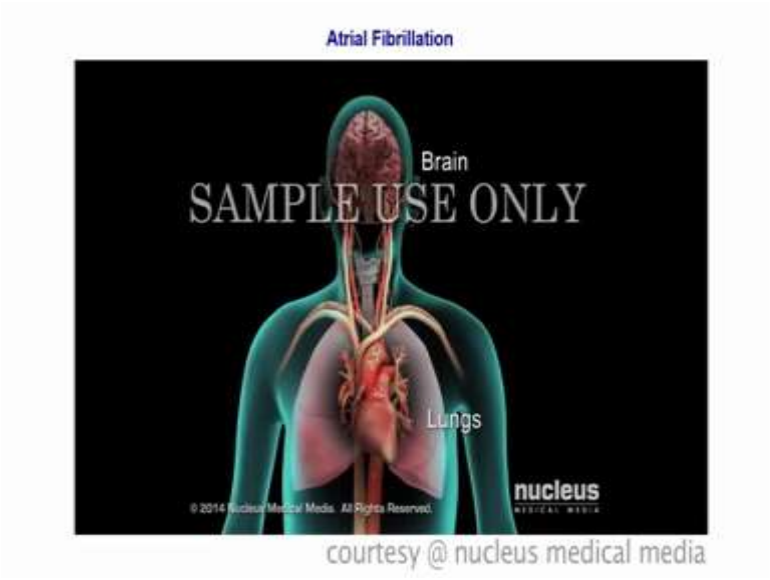

The normal heart rate in rhythm ensures that the livery of oxygen which blood to all of the body organs such as the brain and lungs.

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The group of cells in a heart called the cardiac conduction system uses electrical impulses to control the speed and rhythm of each heartbeat.

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Atrial Fibrillation

Arrhythmia

courtesy @ nucleus medical media

And abnormal heart rate or rhythm called an arrhythmia occurs when there is a problem with the heart's conduction system.

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Atrial Fibrillation

Tachycardia

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Tachycardia is a type of arrhythmia with heartbeats too fast.

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Fibrillation is a type of arrhythmia with heartbeats irregularly and maybe too fast.

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For certain types of arrhythmias, the catheter ablation procedure may be necessary to stop the heart tissue from causing the arrhythmia.

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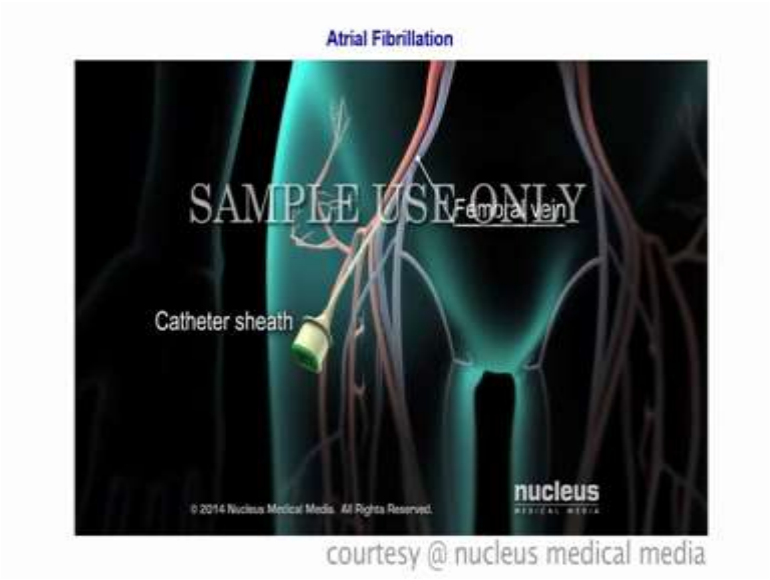
Atrial Fibrillation

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After numbing a small area in the growing with a needle, the doctor will insert a showed hollow tube called a catheter sheath into the femoral vein.

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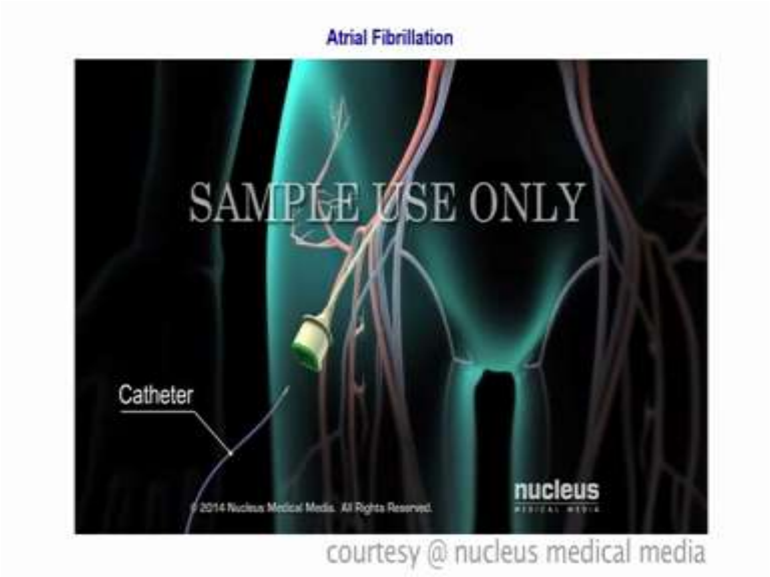
Atrial Fibrillation

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Next, a long flexible tube called a catheter will be inserted through the sheaths.

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The doctor will guide the catheter to the heart through a blood vessel that goes to the heart called the inferior vena cava. The location and progress of the catheter will be monitored.

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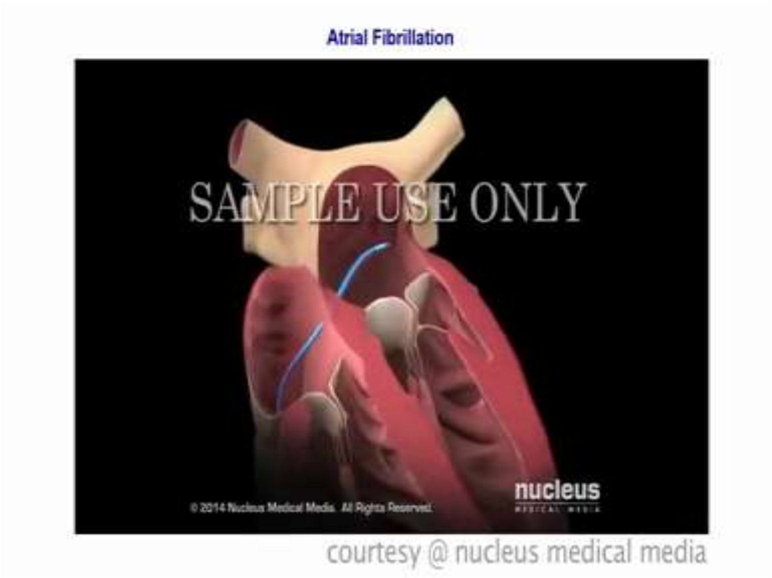

When the catheter reaches the heart, the doctor would guide to the area that is causing arrhythmia.

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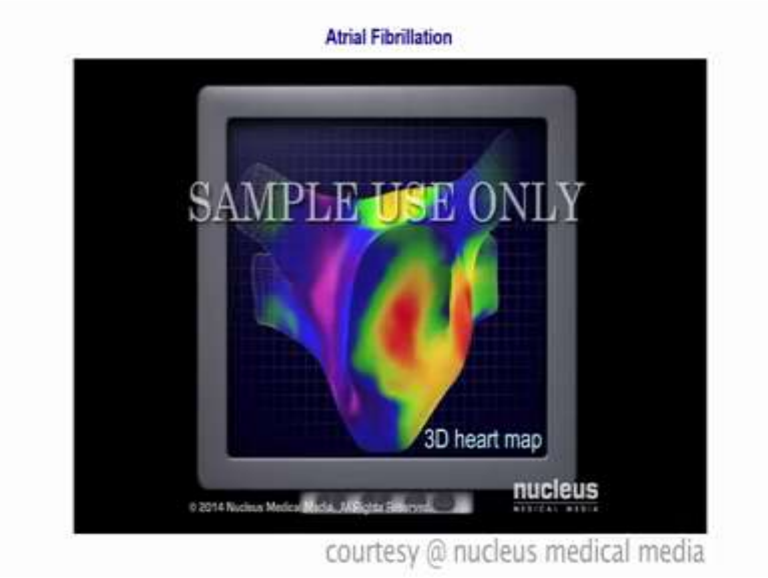

Atrial Fibrillation

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The doctor will find the problem areas using a 3D map of the electrical activity of the patient's heart.

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Atrial Fibrillation

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The tip of the catheter will emit either hot energy.

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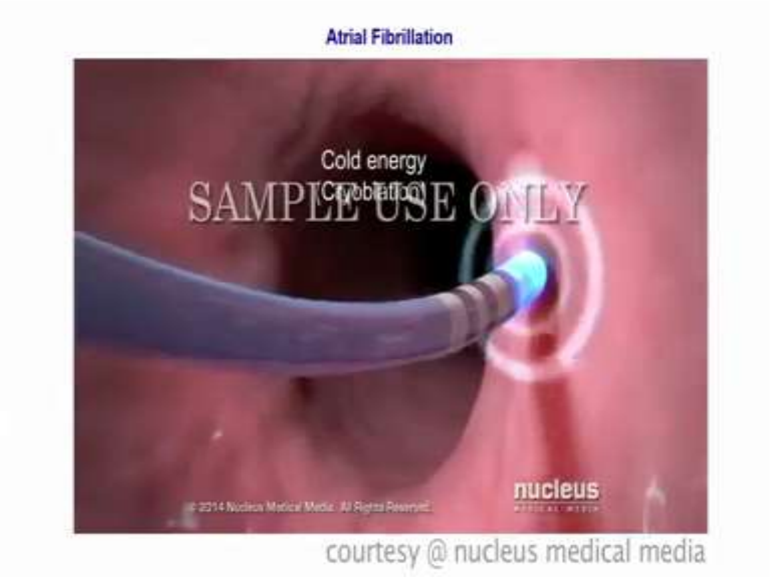

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Or cold energy to ablate the tissue in this area; ablation makes the treated areas stop working.

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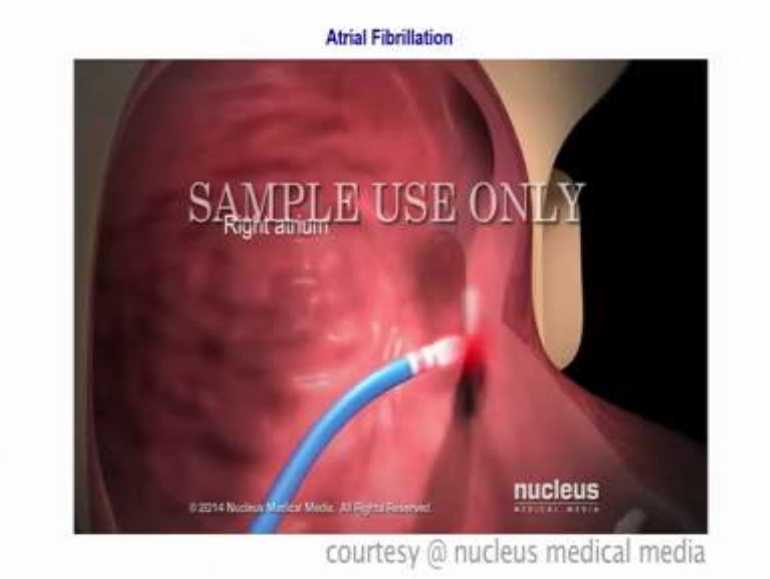

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For an atrial arrhythmia, a doctor will ablate the atrial tissue causing it; if the affected tissues or small well-defined areas.

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The procedure is called a focal ablation.

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Over if the affected tissues are larger areas with more complex rhythm disturbances. The doctor may perform a procedure called ablation remodeling; both types of ablation restore normal electrical impulses and prevent an arrhythmia from happening.

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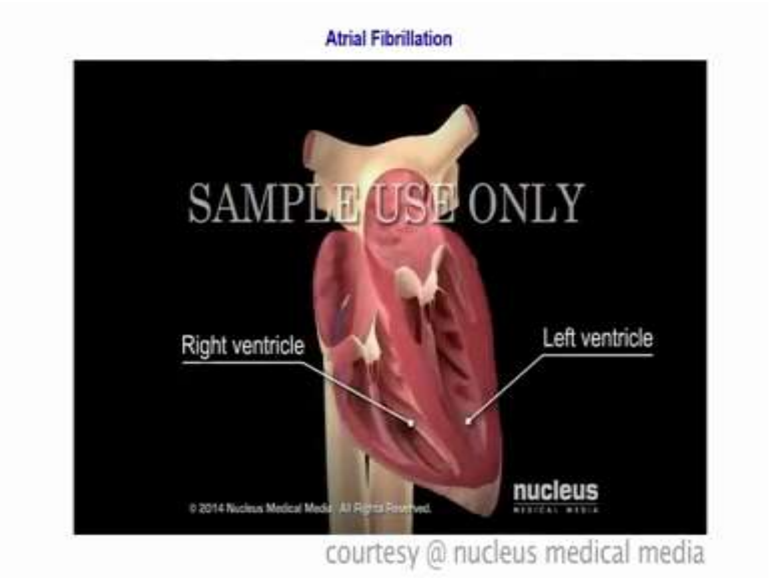

Atrial Fibrillation

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If the cause of the arrhythmia is in the ventricle.

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Atrial Fibrillation

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The doctor can do either focal ablation.

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Atrial Fibrillation

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Over the ablation, remodeling to treat more complex arrhythmias of the ventricle.

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3D Force Sensor attached to the Catheter Tip

Ok; so, in the video that you have seen, in the video, you have seen that the surgeon has to insert a catheter right in the heart and then where the catheter is inserted they look at the electrical signal. So, where is the misfiring of the electrical signal that is called electrical mapping, alright? If you have the heart chamber and if I insert a catheter; a catheter is nothing but the tube right. So, tube and then you and at the tip of the tube, we have electrodes, which are recording electrodes to measure the electrical signal.

Now, once you have the electrical signal they take it, they take the tube out and insert another tube, the tube is a catheter. So, they are inserted on the catheter and then wherever the electrical signal was not correct right that particular region, the surgeon will ablate.

The ablation is nothing but heating right; if you heat the tissue, it will burn. If you burn the tissue, it will not conduct, a technical term, ablation; if I use RF frequency, RF ablation; because I am using catheter RF catheter ablation, right. And when a person ablates or when a surgeon ablates right; he or she needs to understand how much force is applied on the heart tissue, because when you apply want to apply RF on the tissue, you have to touch the tissue right, you have to press the tissue and then you have to going to apply.

So, how much force is applied; if the force is too much, then all other parts which we do not need to ablate will get ablated. If the force is less, then the recurrence is higher; it means, a person would have the same episode after the surgery is done, in both cases are not good. So, how to treat a patient correctly; there is something called transmurality, transmural is where you're when you ablate the tissue, it ablates completely, right.

Because anyway, the heart is also a tissue wall right. So, let us say this is the thickness of the wall, this is the thickness of the wall; if I ablating from one side, how I am sure that the complete tissue is ablated right. It may only ablate half; it may not reach this area right. If I ablate from the front, it may not reach back; so it does not reach back; that means, the front is burnt, but the back is still conducting.

So, I need to make sure that, the entire thickness of the tissue is burnt or ablated and that is called transmural. How to make sure that the surgery has resulted in transmural and how much force need to apply? So, that is why very easy is how to design a force sensor. It is a catheter contact force sensor that a lot of people are working on and I will show you two different ways; first is a very simple way of understanding or designing a 3D force sensor, 3D MEMS-based force sensor we say, it cannot be used in actual ablation.

But, the next version on the same topic I will show it to you that can be actually used in ablation. You reach to the second point, only when you start working somewhere. So, that is how I will show it to you.

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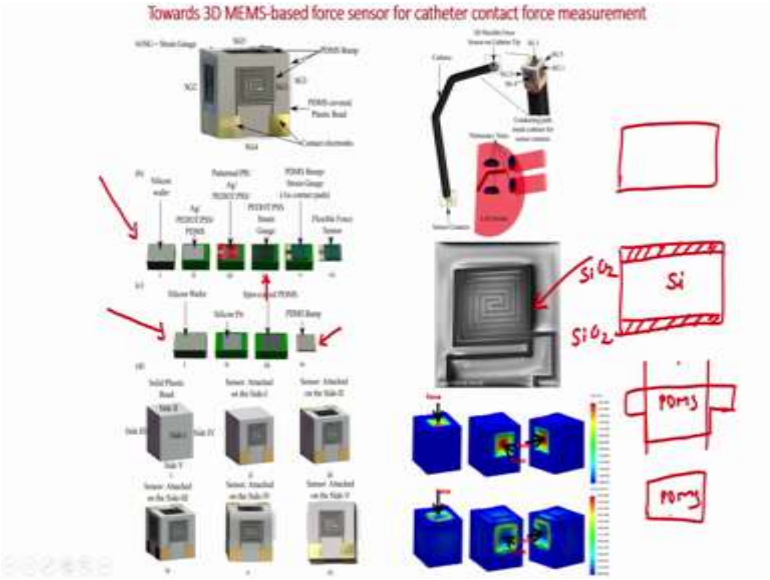

Towards 3D MEMS-based force sensor for catheter contact force measurement

So, if you see here, on the slide we will talk about the 3 D MEMS-based force sensor for catheter contact force, the sensor is nothing, but the strain gauge on a flexible material. Let us see the process flow of this particular sensor; you start with a silicon wafer and then you have a PEDOT PSS over PDMS.

So, you coat the PDMS, you cure PDMS, on that you deposit a spin coat PEDOT PSS; PDMS is flexible material like I have discussed earlier; PEDOT PSS also I discussed it is a strain gauge. And then after you do that you can, there is the silver is used, so that to better adhesion of this particular material, which will help in the patterning process.

Then you have to pattern this PEDOT PSS to form a strain gauge, you can see here; after you do that, you know; so, after use performs photolithography, you have to do this vapor in silver etchant followed by PEDOT PSS etchant and then you form the strain gauge. Strain gauge looks like this right, it is a very simple process, single mass process; you guys now know how to fabricate a strain gauge using lithography, right.

Now, once you have this PEDOT PSS strain gauge, you need to attach a bump on this PEDOT PSS strain gauge along with gold pads. So, first is this contact pads that you can see here.

We need to deposit gold and pattern it such that we have an ohmic contact right from the sensor and then we have to attach a PDMS bump. So, how to create PDMS bump, for that you need to say this one, this particular process flow; you have a silicon wafer and then silicon wafer if I create a pit, if I deposit or spin code PDMS, cure it and peel it off, I will have a PDMS bump, simple, right.

Silicon wafer, silicon pit how to create silicone pit. So, if I take a silicon wafer, I oxidize this silicon wafer, right and then you create a window; create a window using lithography, right. You can remove silicon dioxide using BHF, then you etch silicon; if you etch silicon what will happen, silicon to get etch right. What will happen, silicon will get etch like this; this is what is creating a pit.

Now, if you load PDMS, you can remove silicon dioxide right; you can use silicon dioxide by dipping this for BHF. And if you load PDMS on this and if I strip this off; I have cure PDMS, this is PDMS, I cure it and strip it off; what will I have, I will have my PDMS like this. If I slice the PDMS; then what will I have, I have a PDMS bump right, this is what is shown here, alright.

So, a very simple process is not it. Now this PDMS bump, we will stick it on our PDMS bump; when you stick it on our strain gauge which is fabricated using PEDOT PSS. After this, you can stripe the PDMS substrate from the silicon and you will have a flexible force sensor; easy that is what is a flexible force sensor.

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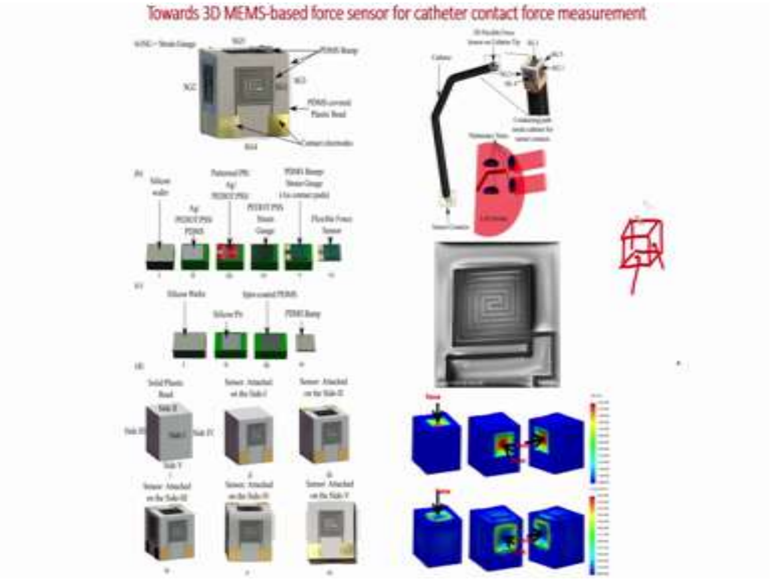

Towards 3D MEMS-based force sensor for catheter contact force measurement

Now, once you have flexible force sensor what you will do; you will make a bid, it is a cube, small cube-like this right and on each side of this cube, you will stick one PDMS. So, there are how many slides, slide 1 2 3 4 5 and 6 right; one slide you will not use it, because you have to attach that sixth slide to the catheter tip, alright. So, you will only attach five sensors on five sides of the cube and this is shown in this particular schematic diagram that you have sensor 1, sensor 2, 3, 4, 5 on all the sides you have sensors. You can do very quick COMSOL simulation, where how much force you apply and what is a stress factor on the strain gauge, right.

So, if I have this, now if I have the sensors attached on this particular cube; then I will have how many contacts, 10 contacts right, because each strain gauge will have two contacts, all these sensor contacts can be brought out from within the catheter.

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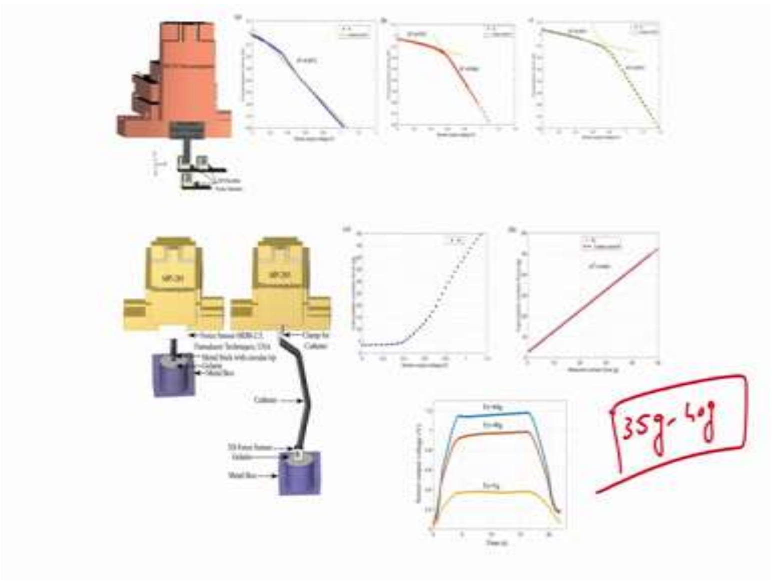

Now, once you have that; first is how you want to understand what or how you know that; what is the change in the sensor values for certain force. So, for that what we do is, we take a commercial force sensor, attached to a micromanipulator and press it on this particular fabricated sensor. When you press it on the sensor, you will see that on apply of compression force what the sensor output voltage.

Now, instead of measuring resistance we can always use a potential divider to see what is the change in the voltage or if you use a Wheatstone bridge, accordingly, you can see the strain change in voltage. So, when you apply a force, known force then you will see what is the output voltage from that you will you can get the data for the fabricated sensor, and from the data you can understand that if there is a certain voltage change; that means, that it is corresponding to that particular compression force right.

So, this is very important, you know the experiment that you need to perform whenever you fabricate any sensor, you have to take a commercial sensor and perform the calibration part ok, this is called calibration, alright. Now I if I want to apply a force onto a tissue, if I go for a tissue before that I have to go for a phantom tissue. Phantom tissue is not real tissue and phantom tissue can be fabricated with the help of gelatin. So, if I take box, like a metal box in which I can have a gelatin right and I take a force sensor which is commercial force sensor right, versus the catheter and I press it on the gelatin; then I will see that what is a calculated contact force versus sensor output and calculated contact force versus measure contact force.

Now, you can very clearly see that this is extremely linear; and that is a good thing about the sensor, the sensor should show a linear change in the output response, for different forces. For example, if I apply 5 grams of force and then remove that force; what is the response time, the same thing goes for 40 grams of force, 60 grams of force, then you can see that this sensor can measure anywhere from 5 grams to 60 grams. And like I said very important problem is, how much force you are applying; the optimum force is somewhere around 35 grams to 40 grams on the heart, alright.

So, when the as you are seeing the catheter is ablating a heart tissue that ablation force should not be more than 35 to 40 grams, this is the optimized force, ok.

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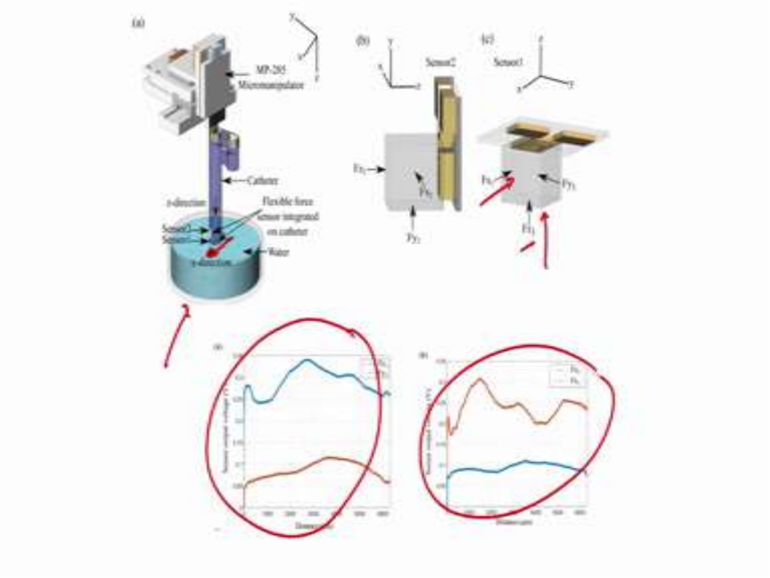

Now, when you actually insert the catheter inside the heart right, then it has to pass through the blood vessels and that is why how the sensor would act when there is a force of liquid media or medium on the sensor.

And for that what this experiment shows is, that if you have the catheter and you have several sensors sensor 1, 2 and then water and if I move the sensor in x-direction or y-direction or z-direction, the corresponding sensors which are attached to the catheter will change it is property, right. And then what we have given notations are, this is let us say F_{x1}, this is F_{y1} and this is F_{z1}; same way if you are taking a sensor 2, then F_{x2}, F_{y2}, and F_{z2}.

So, when I perform these experiments, I can see that based on where the force is acting, I can see that particular you know the values are different. For example, F_{z1} and F_{y2} you can see here it is different right; when I apply force in this direction F_{z1} is different than F_{y2}, same thing F_{z2} is different than F_{x1}.

So, you can very clearly understand that you can delineate the force that is applied on a certain part or if whether this normal force or whether this shear force, you can delineate and that is very important.

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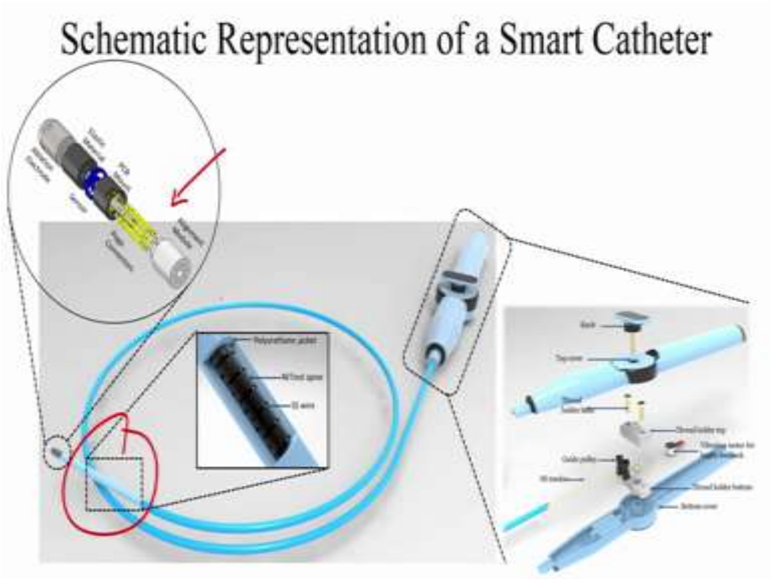
Schematic Representation of a Smart Catheter

So, learning from this all experiments; what now we have thought is, how we can design an actual catheter that can be used for ablation. These are maneuvering system for that particular catheter; maneuvering system is how to move the catheter in the real world, there is a knob, there is a top cover, there are thread balls. Again, you can design this either with 3 D printing or you can use other manufacturing techniques, there is a guide pulley, S S tendon and then there is a vibration, motor for haptic feedback.

So, let me come back to haptic feedback. I told you that there is a force sensor that is required at the tip of the catheter, but at the same time, a very important problem that is there or gap that is there in the current catheters is that none of the catheters has haptic feedback. Haptic feedback means the feeling of force, right. So, how much force a surgeon is applying on the heart, he or she only can see on the display; but cannot feel the force.

So, how about we design a catheter in which you can not only see the force but also we can see the force and that is called your haptic feedback, and that is why we will convert the force values to the haptic feedback. There is a bottom cover and then there is a thread holder bottom; in between, we have also use the nitinol spine, nitinol is smart material, is extensively used in a new catheter and then at the jacket is consist of the polyurethane and this is the jacket we are talking about here, right.

So, that the catheter can move or maneuver and this is the catheter tip, if you see the tip there is an ablation electrode, then there is an elastic material, there is a sensor, PCB and then pogo connectors followed by the alignment modules alright, this is the sensor design.

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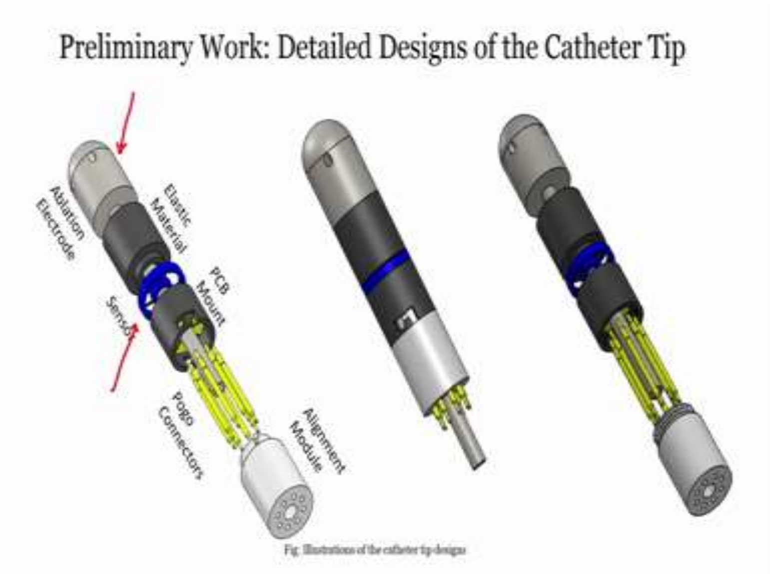

Preliminary Work: Detailed Designs of the Catheter Tip

Fig: Illustrations of the catheter tip designs

And if I go further, then you will see that the block diagram of this particular catheter tip; we are only talking about tip which is right over here, that is it.

So, if I talk about the catheter tip, then you can see that that tip means ablation electrode which is of metal. And then the sensor is right over here, so we are interested in designing the sensor as well. If you lock it together, it looks like this; and then you can see here there are some holes, this is for the irrigation type of catheters. Irrigation type of catheters is the catheters in which use the saline media to make a way through the blood medium.

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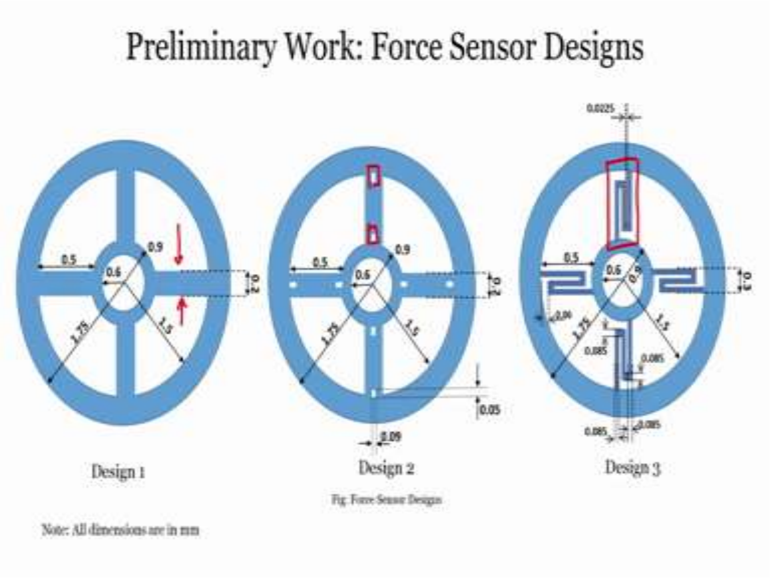

Preliminary Work: Force Sensor Designs

Design 1

Design 2

Design 3

Fig: Force Sensor Designs

Note: All dimensions are in mm

Now, based on this we can design several kinds of force sensors; the force sensor that I am showing it to you here is, the design 1 right, and then we have design 2 and then we have design 3, right. So, design 1 is, that you have the bridges here right, design 2 you have holes in these bridges here, and design 3 you have a meander shape or coil-shaped sensors.

Now, actually the sensor that we will be using is a diffusion-based piezoresistive material and the diffusion occurs right at the tip of this particular bridge like this, like this and then there are two here. I will show it to you how exactly we have designed it; but my point is, we have taken this bridge structure and then made a hole in that and then we have used this serpentine structure just to improve the sensitivity. The dimensions are given here, which is not really important for you.

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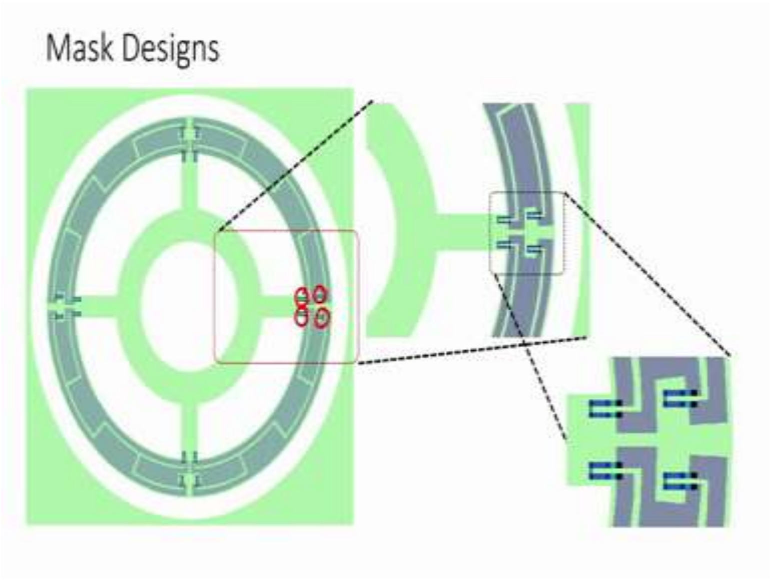
Mask Designs

But the point is, as you can see here we have four strain gauges; 1, 2, 3 and 4. If I have a magnified version of that, then you can see very clearly the strain gauge which is four in number, here are there. So, two they will balance out the other two and we can use the circuit with Wheatstone bridge.

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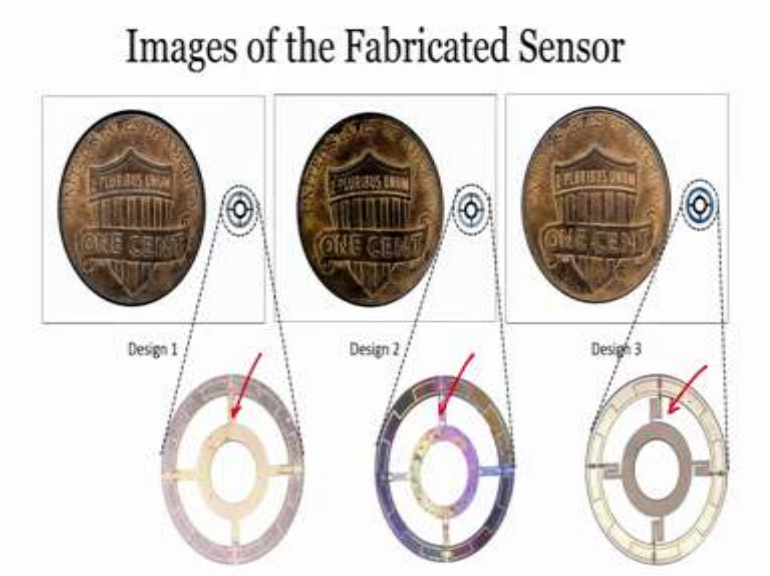
Images of the Fabricated Sensor

We have tried different designs and this is actually fabricated sensors with us right; one with directly there is no hole in the bridge, the second one is there are two holes and the third one is with the serpentine structure, right. So, this is how the sensor looks like.

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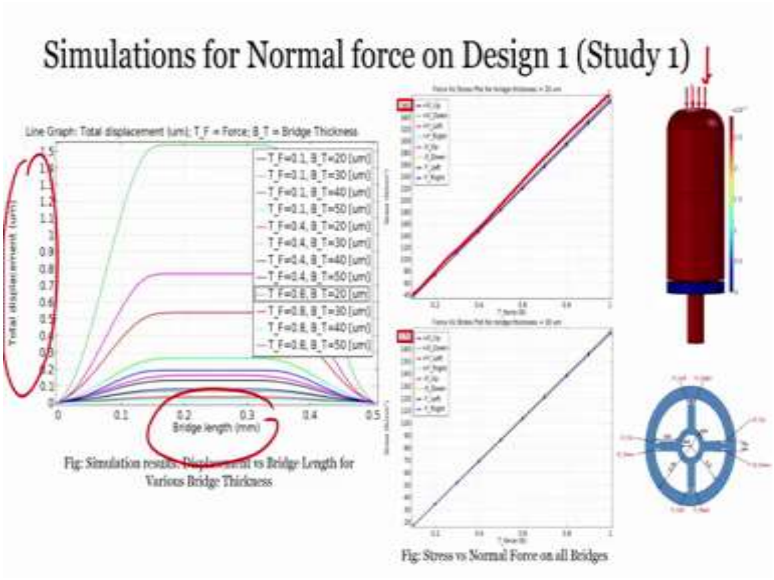

Simulations for Normal force on Design 1 (Study 1)

Fig: Simulation results: Displacement vs Bridge Length for Various Bridge Thickness

Fig: Stress vs Normal Force on all Bridges

Now, if you recall your earlier discussion or earlier lecture in which you had taught COMSOL multiphysics simulation, using the same COMSOL multiphysics you can understand that what can be the optimized design for my force sensor.

For example, if I want to know what is the displacement versus bridge length for various bridge thicknesses, then I can give that values and I can get that total displacement versus bridge length. From that, I will understand, what should be my optimized bridge length for the given displacement, alright. Same way, if I apply a normal force or apply a shear force, how the sensor would behave that is what is given here. You see here that when I apply normal force, almost all this x_{up}, x_{down}, y_{up}, y_{left}, y_{right}, everything is kind of increasing linearly, right.

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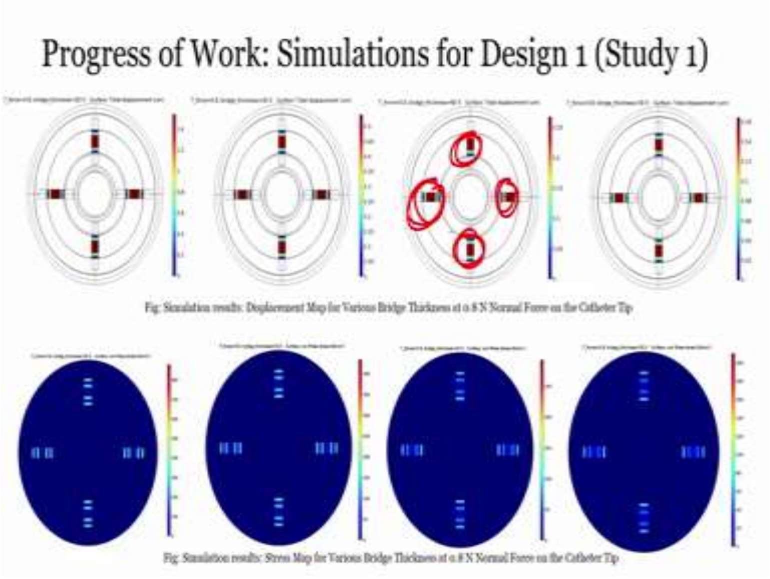

Progress of Work: Simulations for Design 1 (Study 1)

Fig: Simulation results: Displacement Map for Various Bridge Thickness at 0.8 N Normal Force on the Catheter Tip

Fig: Simulation results: Stress Map for Various Bridge Thickness at 0.8 N Normal Force on the Catheter Tip

So, stress versus normal force or all bridges as you can see here, it is very easy to identify if you once you know COMSOL. And here we have shown the displacement map for various bridge thickness at 0.8 Newton normal force on the catheter tip that how each sensor would behave and you can clearly see that this stress is right in the on the bridge; because of the stress or strain, the resistance would change, because these are all piezoresistors, right; these are piezoresistors, alright.

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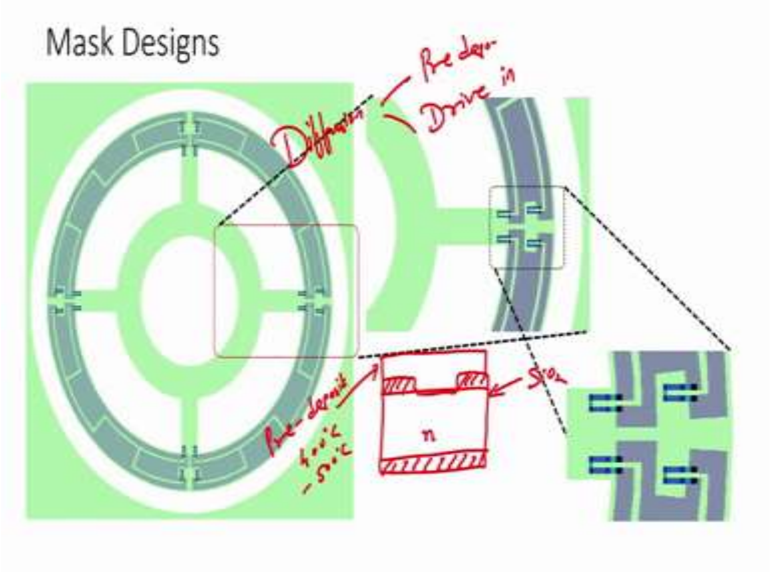

Mask Designs

So, if I let me show it to you very quickly how can you diffuse one single piezoresistor and then you can take it over from there. So, I will just show it to you; if you have an oxidized silicon wafer all right, oxidized silicon wafer, then if I want to let say this is n-type and this is my silicon dioxide, right. What I will do is, I will open a window, I am just showing you quickly ok.

So, that you understand, I will open a window like this. In silicon dioxide and then I will spin coat my boron. I just spin coat there are different ways of diffusing boron, or impurities into silicon wafer; one is solid, then another one is liquid, and the third one is with the gaseous phase. We will use a liquid phase just for this particular class and in that, you can spin coat this boron on this particular silicon dioxide or an oxidized silicon wafer with the window that you can see.

Now, after this, you have to. So, when you discuss diffusion, diffusion has two processes; one is called pre-deposition, second is called drive-in. So, you have to first pre-deposit. So, you have to anneal this or heat this around 400-degree centigrade, 400 to 500-degree centigrade, ok; once you do that this layer will start like this, just a little bit into this silicon wafer, alright.

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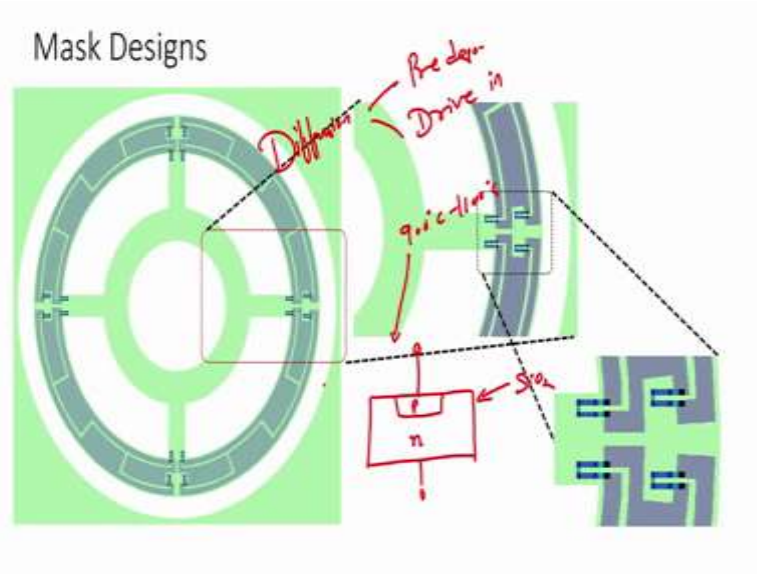

Mask Designs

Now, if I heat this further which is called drive-in at higher temperature or let say around 900 degrees centigrade to 1100 degrees centigrade right, this will start driving in and form a diffusion layer. After that, you can dip this wafer in SiO_2 etchant and this everything will come out. So, now, what you have is, you have a p material, n material; if I take contact from here and if I take contact from here, it becomes your p n diode right, but we are not talking about p n diode, we are talking about diffusion.

So, now we have this p types of this was a boron-doped in the n-type wafer; if you were open a window in this particular fashion, then you can have a string gauge, this is a cross-section of that. So, now, once you have four of those, how can you connect it, you can connect it with the metal deposition and then we will also see if possible if the time permits that how the process occurs.

So, I will go to the next study right, after this. So, that is why I was showing it to you how diffusion occurs; because when there is a force on these particular bridges, there is a change in the strain which causes the change in the resistance.

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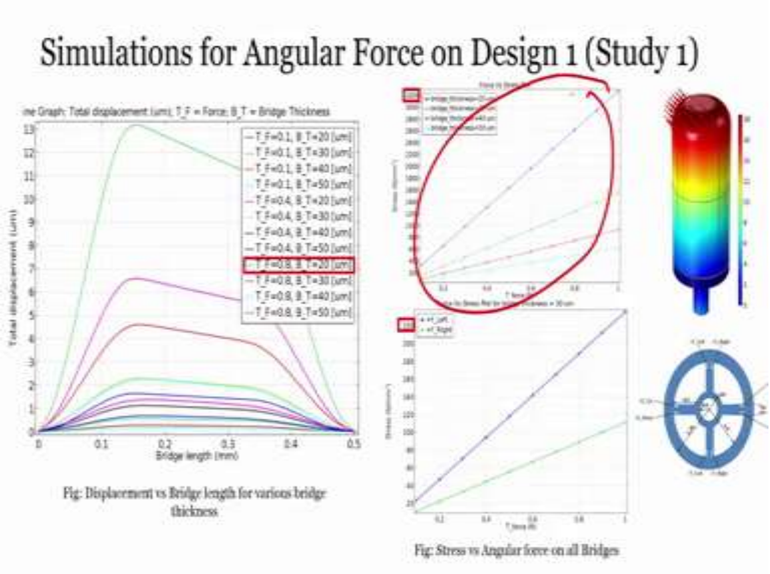

Simulations for Angular Force on Design 1 (Study 1)

Fig: Displacement vs Bridge length for various bridge thickness

Fig: Stress vs Angular force on all Bridges

Now, instead of normal force if I have angular forces, then how my sensor would behave. I can have all the simulation data here, which sensor would or which side of the bridge would have more stress compared to them with respect to each other. And here also you can have stress versus angular force on all the bridges; you can see very clearly that you can delineate those parameters if I see the simulation results for the piezoresistor length.

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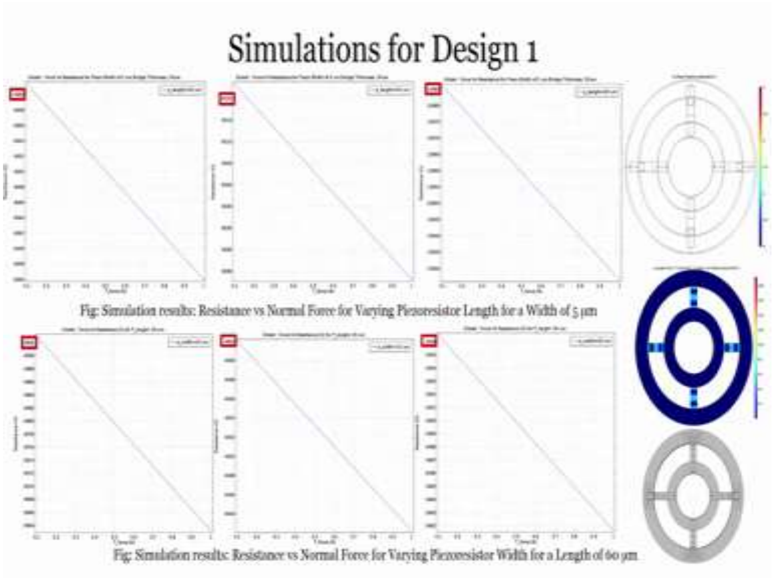

Simulations for Design 1

Fig: Simulation results: Resistance vs Normal Force for Varying Piezoresistor Length for a Width of 5 µm

Fig: Simulation results: Resistance vs Normal Force for Varying Piezoresistor Width for a Length of 60 µm

Now, the first one was about the bridge right, what is a bridge thickness, bridge length; the second one is what is a piezoresistive thickness, and a piezoresistive length and width. So, for the line width of 5 microns and if a line width of 60 microns, how the resistance versus normal force changes for a given piezoresistor.

This is all simulation results that we have done and you can see and then once you have this all the data; what you can do is, you have to use this catheter into the heart, and which heart you can use pig heart; because pig heart is very close to the human heart. And in that pig heart, you can use this catheter and get all the data from the catheter right; whether it is the force sensing data or you are going to ablate that tissue, you can use the pig heart.

(Refer Slide Time: 31:48)

Ethics Committee and Biosafety Committee Certificates

Institutional Animal Ethics Committee
Central Animal Facility
Indian Institute of Science
Bangalore - 560 012, INDIA

CERTIFICATE

Prof. Umesh Varshney
Chairman, IAEC

CPCSEA nominee

Ethics and Biosafety Clearance for Cardiac Catheter Studies

Now, to get the pig heart again you have to get the ethic clearance; and for ethic clearance, you have to apply the Institutional Animal Ethics Committee. So, we have got the ethic clearance and then we also got the biosafety approval clearance, so to use a pig heart in our laboratory, alright. So, this is how the cardiac ablation will work. I would discuss other topics in the next module right; till then you take care of any questions feel free to ask me. It is not so easy to grab this kind of application, these are a little bit towards advance research or application of your sensors for health care technologies with a little bit of advance side, ok.

So, you may be confused in some of the slides and if you feel free to ask me questions, ok. But if you again go in-depth, it is nothing but a force sensor that we are developing with the help of strain gauge, to make it very simpler. Whatever force sensing data we get, if we can change it to the vibration mode right; then the surgeon will also feel how much force he is applying or she is applying on the heart. There is an idea and that is why I said smart editor instead of just catheter, alright. So, I will see you in the next lecture, till then you take care, bye.