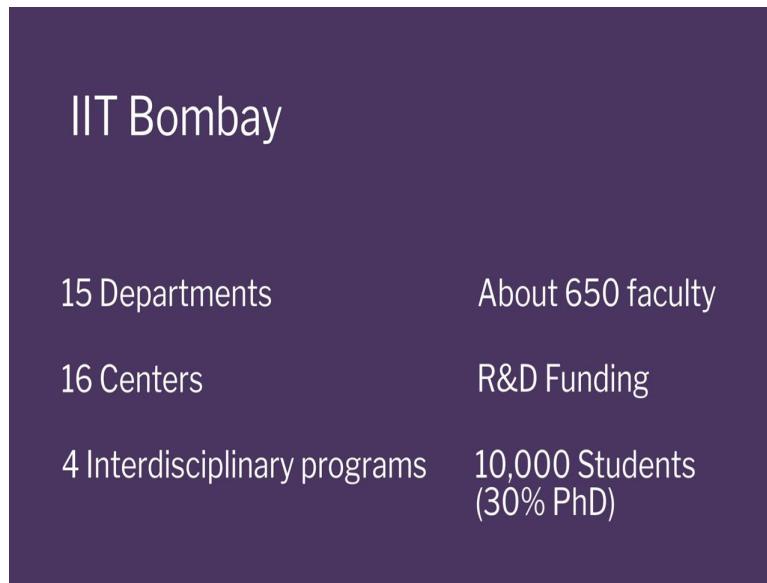


Design, Technology and Innovation
Prof. Ramesh Singh
Department of Mechanical Engineering
Indian Institute Technology Bombay

Lecture-8
Technology to Solution

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And then, I would just like to give you some details about IIT Bombay. We have 15 departments, 16 centers, 4 interdisciplinary programs and about 650 faculty members, a decent amount of R&D funding, 10,000 students, give or take, out of which 30% of our student body is PhD. So, despite what we think that it is a UG centric institution we have a significantly high number of PhD students. And a few of them work in my lab who are involved with these kinds of product development and basic research which leads to product development. And then we have support staff and infrastructure which actually supports our research.

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Mechanical Engineering Research Areas

Micro/Nano technology

Computational Methods

Fluid mechanics & thermal sciences

And I am part of the Mechanical Department. The Mechanical Department does a lot of things. Some of the key areas of research are something called Micro/Nano Technology, Computational Methods, Fluid Mechanics & Thermal Sciences,

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Mechanical Engineering Research Areas

Manufacturing

Bioengineering

Manufacturing, then there is Bioengineering, basically that is the need of the hour because a lot of the products of the future, related to healthcare and also to enhance our quality of life. And this is Solar power & Energy, because energy again is a big issue, so we want renewable, sustainable energy and solar power is also one of the focus areas of research.

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Research- Micromachining

Additive micromachining

Joining/ welding

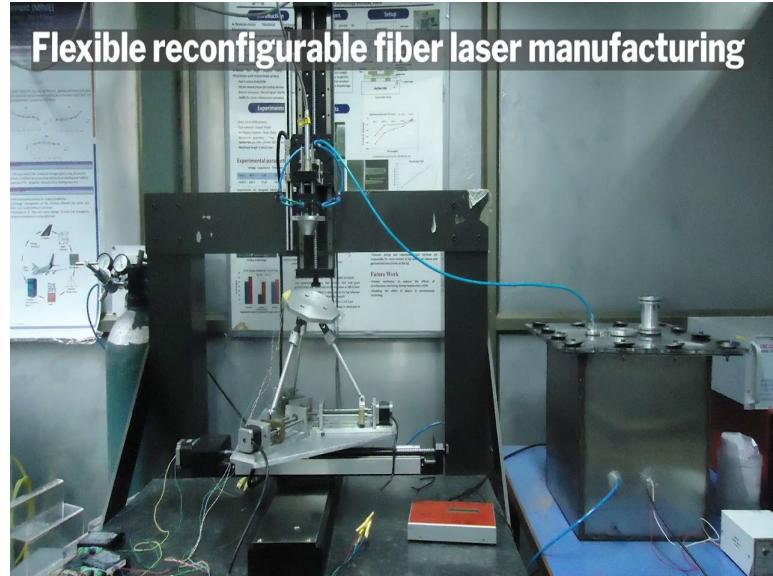
Casting/ Forging

Mass conservation process

So, the basic research area which I do in my lab is. The first one is Micromachining. So either I can subtract material, which will be machining. Machining are of different forms. I can do Tool Based Machining, I can do Electrochemical Machining, I can do Electrical Discharge Machining, I can use different things to remove material or what I can do is I can add material which is, which we do in Additive Manufacturing or I can do joining kind of a process, where I can do weld, multiple things and make a product out of it or I can do something like Casting and Forging which is Mass Conservation process.

We do not really develop the process, we also develop the machines to work with it because these machines are commercially, some of them are available, very few though but they are very expensive. So, I am innovative and I actually go ahead and build those machines. And then once you build the machine there are some challenges with the process itself, because the tools which I use, just to give you some idea what tools I use in machining, can be one-fourth of your human hair. 20 microns.

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The second thing, what I do is, I call it something called Flexible Reconfigurable Fiber Laser Manufacturing. The reason I use that is that I do not have money to buy 5 different machines. So, what I do is I buy one laser and I and I basically make changes to the spot size, the powers.

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So, basically I can do very high energy intensity to ablate the material, sometimes low to heat the material so I can, I can melt the material, I can heat the material, I can vaporize the material using the same laser by changing the optics.

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And a combination of other things, to do certain things so do like, texturing, sometimes hardening, sometimes adding material and printing. So basically printing is nothing but you add powder and melt it and create layer by layer a structure.

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So, that is what you do so I actually do all those things with lasers. Then, since I teach mechanical engineering I have to understand what is happening mechanics wise.

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Since I am doing all these things these days, everybody's doing bio right? So I said I cut steel, why don't I take a tissue? So, a couple of students what they do is they try to figure out that if I take a tool and poke a tissue what will happen.

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Earlier days people used to just do a big incision and do the surgery. Nowadays you can come out of surgery in a day because they do a very small thing and then they would do something called laparoscopic surgery. They will put a Cannula and then they will put a tool which would go ahead and do local surgery. Now they are not seeing it although they do have some cameras to look at it but they do not have full vision now.

A lot of it depends upon the feedback, so I am cutting liver. I am not cutting something around it. Right? So, they feel it. So a lot of it would be how the force response of a tissue is. So, we want to study that and then get that idea to make some simulators or make some tools where people have a feel, a priori, before he does the first surgery. If he has done 10 surgeries, it is okay. But then how do you make sure that the guy goes and does the right things because bone feels different, liver feels different, stomach tissue will feel different.

I have to go do liver surgery and I go cut my stomach. The only way, the only thing stopping me is: Stomach feels different. If I am poking there it feels different. Create more realistic surgical simulators. We only have managed to just get the forces from different models. So this haptic feedback will be based on this knowledge that what tissue gives what forces. So, this information will build the backbone of it.

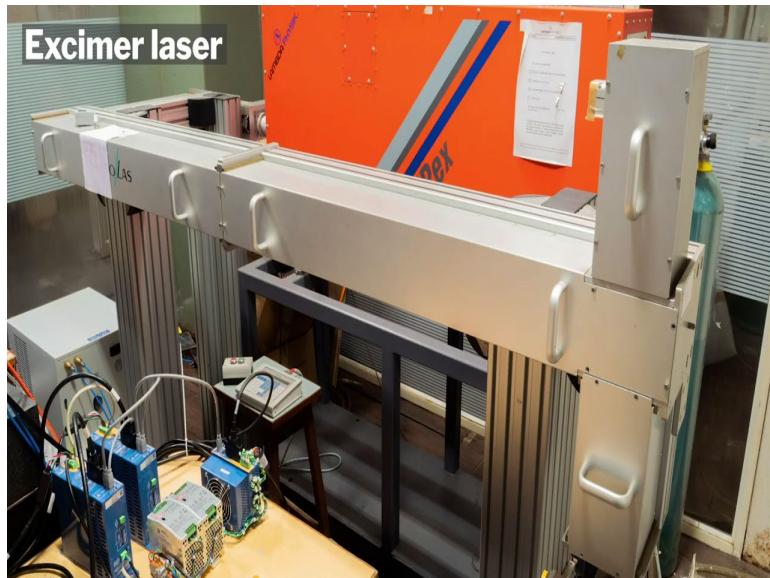
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EMCO Precision CNC Lathe

Now these are some snapshots of the lab. We have a whole bunch of machines since the name is machine tools lab, all we do is we have a lot of tools.

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We have Excimer Laser

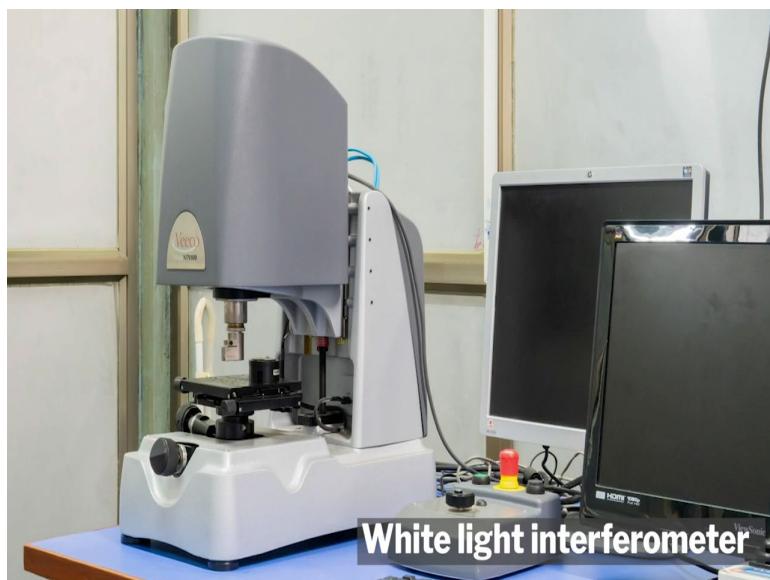
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Wire EDM machine

Wire Electrical Discharge Machining.

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White light interferometer

We have something called White Light Interferometer for surface roughness measurement. So, if you machine something we need to measure the roughness, that is the tool for that.

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There is a Micro Machining Center. It is a commercial thing.

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And then Measuring microscope;

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Stereo and metallurgical microscope

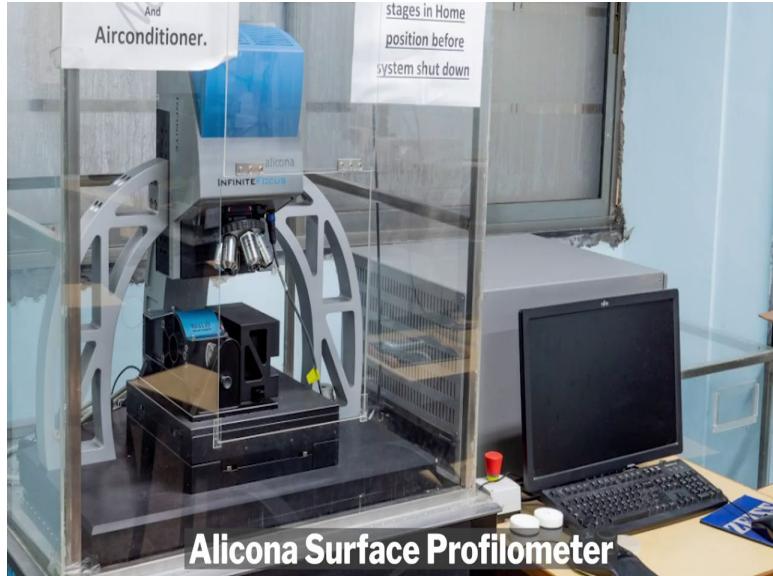
We have lots of Surface Roughness and Metrological microscope, because what we make, right?

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I do micro machining, so I should be able to measure things which I do.

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So, a lot of these equipment actually help me measure what I do. So, I need to be, to be able to measure a few microns, if I am making a channel of 100 microns. I should be able to measure it.

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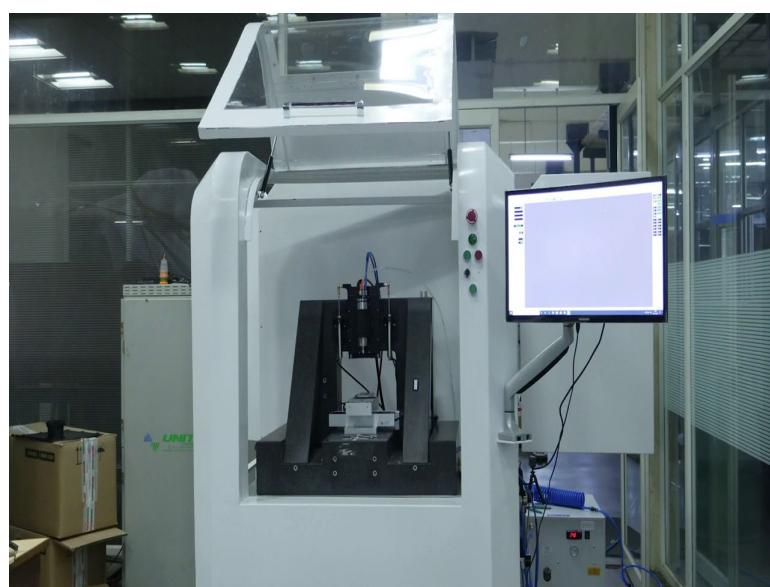
This is called a coordinate measuring machine, so what it does is any shape you make, it can give you an exact measurement of it. This is a very old machine which we have in our lab but the newer ones can give you 3d models. You just put the product, they will take data all around it, they have, they have a probe that will go and get all the data surface data and build your 3d model out of it. A lot of my money which I do in my research comes from industry.

And the industry typically, if I take money from the industry, I have to give them something. So this is what would be probably of more interest to you being design students.

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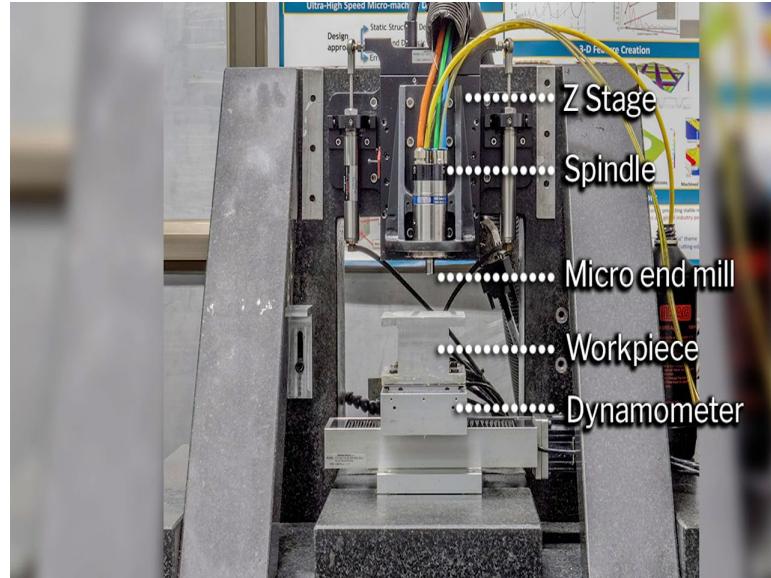
That, how do I go ahead? So they come with the problem, right? So, then I have to interpret the problem in a way which makes sense to me, have a path to design it, have some engineering analysis to back it up, whether it will work or not. And then finally design and build it and it should not be ugly looking.

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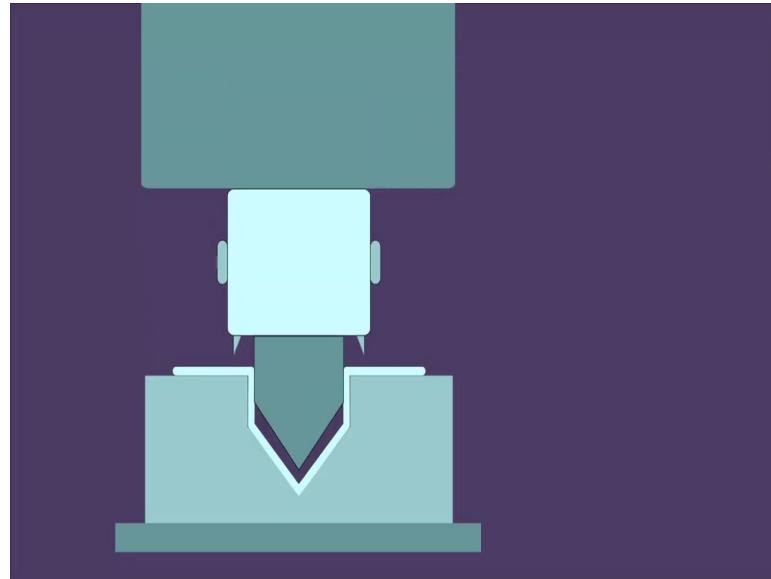
We designed India's first Ultra High-speed Micro Machining Center.

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That I told you that there are processes for forging, right? Where, what you do is you heat the material and shape it using a forge using a dye or a mold, right?

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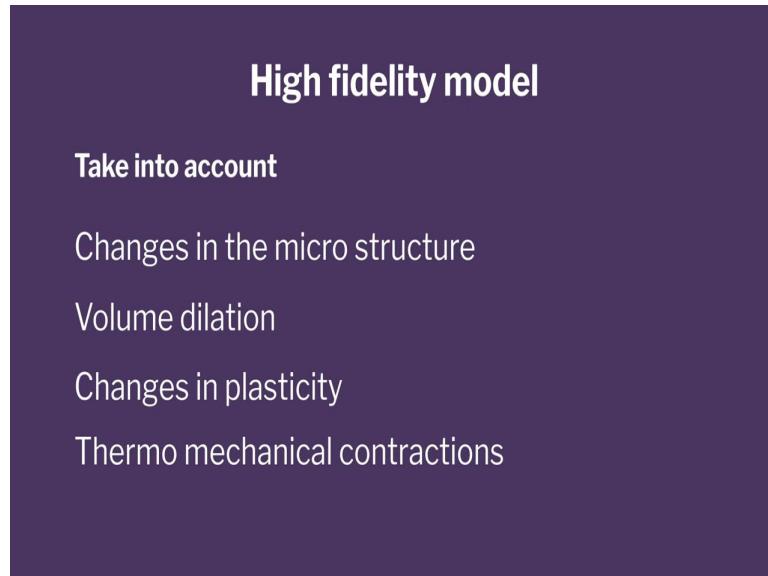
So what happens is after a while since you are taking hot metal and usually compressing it. right?
It can wear, so basically what will happen is, it will not have the correct shape after that. right?

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And if it has cracks eventually it can actually crack and break. So, these things are fairly expensive. Each mold can cost you up to 30, 40 lakh rupees. Just one mold right and you can just throw it away.

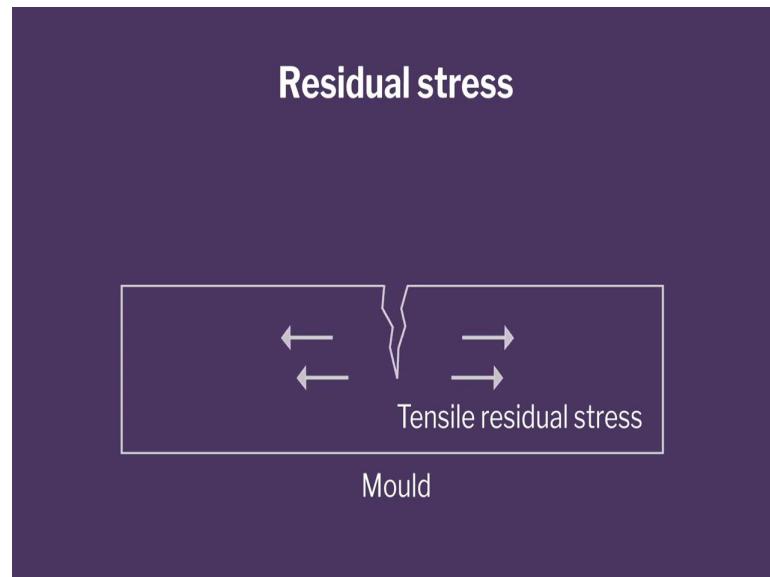
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So, we have developed a very high fidelity model, which actually takes into account if the material melts and re-solidifies, there are changes in the microstructure. And this changes what they do is, they create volume dilation and transformations in plasticity. And there is thermo mechanical contraction because as the material cools it will contract, and this contraction will not be even because the higher temperature will contract more the lower one will contract less.

So, there will be a differential contraction post cooling. That will create stress. And then there are transformations in the microstructure because you cool it very fast.

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All of them will have a role in the residual stress. For those of you who (don't) know what residual stress is, it basically means that the moment I cool and everything there is no load, still there will be a stress in there, locked stresses. What it will do is if it's tensile, right? And there is a small crack. The tensiles will open the crack. So, your fatigue life gets compromised. So, if I do it just by depositing, not knowing what kind of stresses are evolving, not understanding the process, I barely do a job which will fail again in 3 cycles, do 3 more forging and again it will fail.

So, if I understand the process mechanics, do it the scientific way, with the scientific knowledge I will probably be doing something which has a much longer life. So, that is what I am making a good case of doing it scientifically. You can do it, but if you do it scientifically, it will be more sustainable. Whatever technology you are developing has to be enabled by science.

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Now, so what we proposed to do in this is, if somebody comes to me and says that we have to develop or prepare for that, you know what I will do? I will actually first create an automatic scanning system. It will go ahead and scan. Compare it to the solid model that what is the actual product look like, and then it will identify, ‘this is the defect, these are the defected areas’. Then it will go ahead and take a powdered material and then do a local 3D printing. Local deposition of the material there. And at the process parameters which will not create undesirable residual stresses.

So, the process parameters will come from science and the technology is the actual product and the system preferably that goes along with it. So that is what we propose and we call it the Autonomous Damage Detection system. The Material Deposition system and the entire thing which will come into one package would be called the Restoration system.

Student: Filling of deformities layer by layer, does that create some problems like from the actual material which is?

Sir: Yes it will, so you need to know what it will do. Most of the material which I make by forging it is actually, properties are the same everywhere.

But if I do layer by layer the property variation will be there. And then I build another machine for BARC. They needed very high speed bearings, very, very high speed bearings. And these things have to run 15 years non-stop. So, it has to be very reliable. Now they want to change the material

from something what they use right now to sapphire. If I have to machine sapphire, what will be the biggest challenge? Crack is a big problem because it is a brittle material and you need something harder to cut because sapphire as it is very hard.

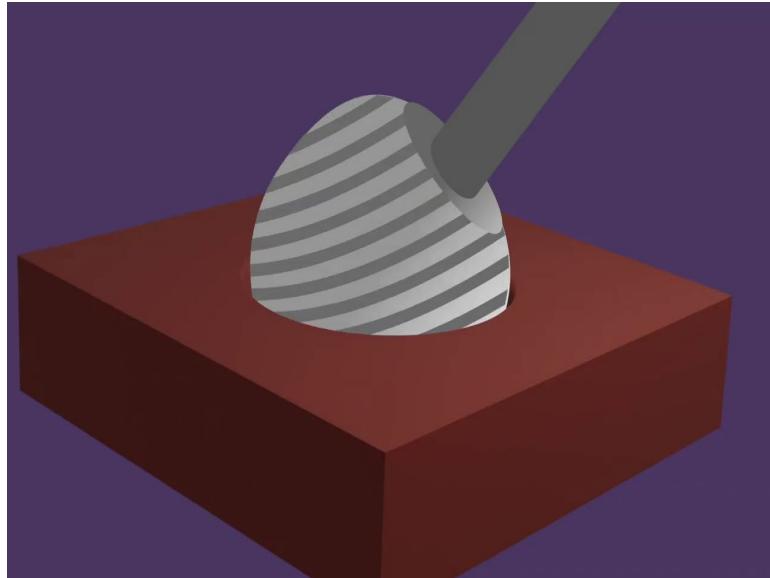
So, the problem was, whenever you machine you will create some cracks and the only thing you can use to machine is diamond. So, either you buy a super duper expensive machine to do something like this which there are very few in India. So, we said that okay we will do it cheap. I will run it in my lab, I actually machined it in my lab with some crack in it, little bit of cracks minimum possible. I actually cut at 1 micron depth of cut, if you can imagine. Pushed it to the limit, still there were some cracks.

To take care of that we developed the polishing process, and it's a very funny polishing process. I have a cavity to polish, how do you think I should polish this cavity? If I have a cavity to polish. Of course chemical is a good idea because then chemical dissolution would enhance the thing, but even to do that chemical digitations evenly all the way through, I need to make sure that there is relative motion between the, all the points here.

So, the first thing that dawned onto me is, do *idli* and *dosa* thing. Make a ball that conforms to the thing and it just moves. Now what will be the problem if I do something like this? The corners will rotate, the velocity will keep on going smaller and smaller at the center, it will stall so there will be no polishing in the center. So, what we did was we did two things one we did it 45 degrees and then we rotated the ball also.

So, we did a double movement. So initially what we did was we did something like this. We did a motion rotating, a rotating ball with what they do in the *idli/dosa* motion. That was a very kinematically very un-smart of doing it.

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Then what we did was we did this, and at a very precise location we started rotating the ball itself, the cavity itself. So, now there is non zero velocity everywhere and build a machine like that and of course we use something that chemically reacts to the surface, so, the combination of mechanical and chemical polishing, and gave the machine to BARC.

One of the guys from CEAT Quality Control came to my lab and said that when they build these tires, right? So what happens is there is misalignment between those edges.

Once the misalignment is there, regardless of what we do, everything is a waste, and when they do the first pass of the tire building, there is a drum roll and that tire that, basically the rubber piece is rolled over it, is fed automatically and gets rolled over automatically. Now what happens is if the alignment is off, so they have 2 laser markers and the guy eyeballs it. The requirement is 3 millimeters over 1.6 meters and he eyeballs it like this. If it is not right he will take it and do it again by hand.

Each time he does it, he could have built four tires automatically. Each time he unwinds it, he is losing time for 4 tires of manufacturing. So, they came up with a solution. They come and tell me what we will do is, we will take a scale and measure it. I said how on earth you can measure 1.6 meters and get a 3mm accuracy with 1 mm least count of it. How do you even see it? So one guy will see there and the other guy will see there and say here there is 1.5 and here, there it is 1.5 mm. I said this is crazy. It is not going to work.

Then he says then what I will do is I design a special caliper exactly the same which I want and put it there. I said you will use a caliper on a rubber, on a compliant material. 3 mm will compress it. So every time your product will be right. Put a caliper, it will just compress the material, compress the, it is a compliant material, it is rubber, right? So I told them the only way to do it would be that you have a good vision system. Take a camera, measure it real-time, measure it very fast, do it at various locations while the tire is rotating.

Locate it as every location, so I said every 10 degrees get the data and then do it. So we actually build a system for them. Every 10 degrees it measures, it actually takes the laser mark, identifies the edge, measures everything how much of it is, computes real time and tells the operator it is good or bad and logs the data to their quality system. So, the entire system we design and built for them. Now this went out fine. One of my old students who has a company now designed everything.

Now what happened was they came to us and said that we have another problem. This is what I will talk today, primarily the Vent Cleaning system. They came to my lab. ‘Oh you use lasers we have a problem’. The problem what they defined was very simple. They said that we have these molds right. So, tires you know they will take so all these threads, it is actually molded. So you take tire and you take a heated mold, get those shapes, cool it and take the tire out.

Now what will happen is all these molds, any mold will always have vents because the material has some porosity, so the gases will come out. So, the gas has to be, to come out and these vents should be there. So, these vents, what happens is, if I do it say about, 1000 odd cycles of molding, these vents get clogged. And if I do more of it with the clogged vents the quality will get compromised. Because my air will not escape, so there will be porosity in the product. You do not want that. Right?

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So, the way the clean it is, somebody actually takes a drill, 600 micron drill, and by hand each tire has 1600 vents, 1600, somebody goes and does it. You have seen a new tire. Right? Each tire will

have a hair like structure. That is called a spew, vent spew. So that hair like structure is because you have vents. So, you will actually, new tire, you will see everywhere, even on the radial face, but on the sidewalls you will see even in the old tire, if you look at the sidewall that these tires will, these spiky things will always be there even in the older tires.

Those are vent residues. So this is what actually goes into the vent and that is what needs to be cleaned. So, they will take a thing and (tap tap tap tap tap) they will clean it like that. But that is a process where it is inherently very dangerous. Tool can break, if the tool breaks what will it do? So, it can be in the vent that is also not required and for those of you who have never done drilling, if a drill breaks in a hole while drilling, taking that thing off is a nightmare.

Ek to hole gaya (One is the hole is gone) and then the other thing would be that, to take out is a bigger thing, right? So, now that is one issue which is there. So, what happened to them, the CEAT guy is, they actually gave a tire with metal embedded in it and their entire batch was rejected by Renault. These guys come to my lab (and say) ‘You use lasers, can you do something? Can you design something which actually just removes all this drilling business?’

I said ‘why don't you send me the molds. Let me do some experiments. We will use lasers to see whether we can clean these using lasers or not’. So that is how this product evolved.

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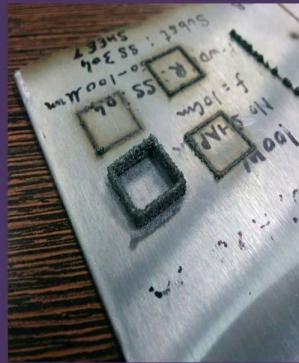
Then a lot of these diamond guys come and worked with me, because they polish diamonds but they never knew what they were producing. So, they came to me and said that, ‘You know, I have an idea. I want to do digital personalization on jewelry and gemstones’. So, I said ‘What do you want me to do?’ So he said that ‘Can you do some digital personalization?’ Every jewelry which somebody buys is unique. You can create an app where you can have a unique code on the jewelry. Somebody scans it, the moment you scan it that unique code is linked with something on the web where you can have your love letters, pictures, messages, blah blah blah, photographs pop up. So, that will be a digital personalization of the jewelry. A jewelry will come along with a lot of things stored. It will have a unique optical code. So, I said ‘I can actually make those codes’. So what I will do is I will machine this small, small array of codes. Actually these are just a bunch of arrays of holes.

Each array of holes once it is scanned, it actually gives me a unique code. It is like a barcode or something, but since you cannot do it on jewelry it will look cheap. I will actually create a slightly fancier design, micro machine it, of course with tools or lasers and then you can do it. So, the only problem with that would be that that has to be amplified. So, I will give them a magnifying glass, a lens attachment with it. So anybody who buys the jewelry will get a lens attachment free with it, with the jewelry, which goes into your cell phone.

So that will be an additional tool which will be given to the guy who buys the jewelry: a magnifying lens. The ideas do not come in vacuum. You need solid science behind it to generate those ideas. So, research is the driver for those things. Unless and until I know about lasers I would not be able to make this machine. So, I have some idea based on my scientific background that I can extend it to a product or extend it to a more marketable idea.

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Why Scaling Down?



Restoration
Laser clad ss box

Now everything every small component has been scaled down.

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Why Scaling Down?

Biomedical



Ti Spinal implants

Machined graphene
cantilevers

So, the scaling down can be in various fields. It can be in biomedical,

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Why Scaling Down?

Defence



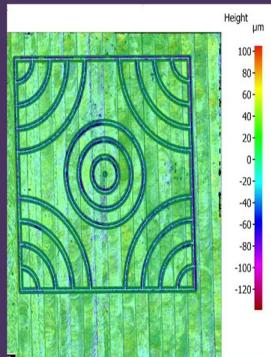
Safe & arm parts
for Bofors shell

Micro-holes

defense applications,

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Why Scaling Down?



Jewellery

jewelry,

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Why Scaling Down?



Electronics

electronics,

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Why Scaling Down?

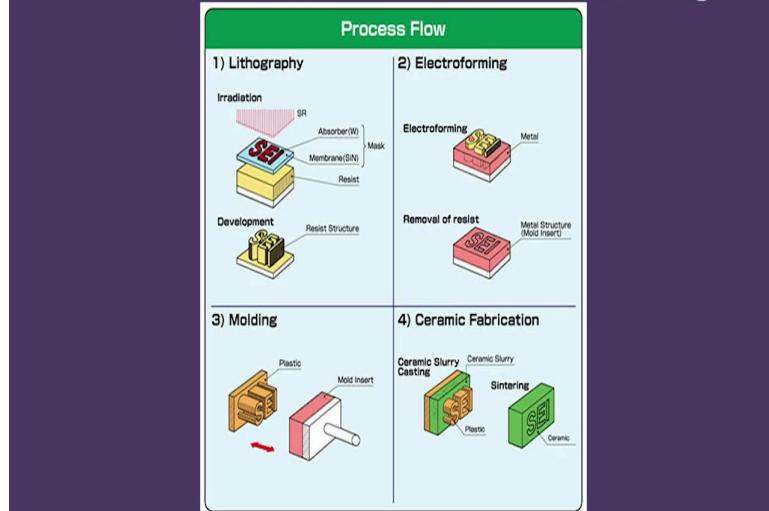


Micro-mold

molds for small features. So there is a huge amount of scaling down of things. But traditionally I do not know if you understand, people still used to make a lot of small things.

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Traditional methods for micromachining



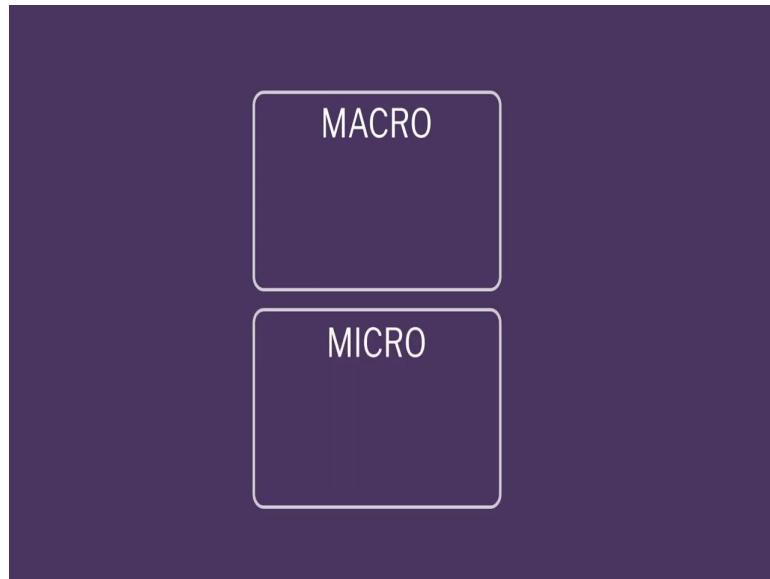
People were making (electronic) chips since the 60's. So they were doing it. The only thing the way you used to do it is they will make a mask somehow,

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and then they would shine a laser on it or UV lamp on it and then they would etch it out. It is called the photolithography process. But then that will do only two and half deep, (and are) still used. All the chips that are manufactured as a seven nanometer technology which is there, the cutting-edge technology, uses lithography, still. But they are primarily for silicon, and that is a process which you do not want to scale up and it will not be used for every material.

So what I say is there is a Nano scale manufacturing which is good. We have the technology for it, great. I have a macro world where all my machines are there.

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In between there is a micro scale where either I have to come from top, or take these processes up there. That is a gap. All those lithography processes work for silicon. So, if I have to use titanium, steel, all these metals, it is not easy to do. So, why do not I take the macro scale processes (and) scale it down.

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Scaling down manufacturing process

Subtractive process

- Milling
- Drilling
- Turning
- EDM

So, processes can be milling, drilling, turning, EDM. Now what is the primary problem?

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Scaling down manufacturing process

Issues with scaling

- Fundamental science not well understood at micro scale
- Technology challenges

The primary problem is we do not understand the science also at that level. As I told you one example. right? What stiffness does. The stiffness scales nonlinearly, so we have to design a process in such a way that these forces are very very low. Any small force will break that tool. So fundamentally what we said is the way to counter that would be that you go at 100,000 rpm. Normal machines run at 3000 rpm. The problem with going at very high speed is that for those who do not understand dynamics: Certain frequencies can be excited.

Any misalignment, if there is even at-of misalignment, it will be amplified, $\Omega^2 r$, if you remember that. So there will be alignment miss-amplifications, misaligned amplifications. There will be some of the natural frequencies, (which) will be excited and any small vibration with a very low flexibility, low stiffness tool is very dangerous. The tool will break. So, you have to understand the science of dynamics very, very well in the machining process to be able to make it properly. That is a big challenge. So, I can make a machine but to operate the machine I need to understand the process very well.

**Design, Technology and Innovation
Prof. Ramesh Singh
Department of Mechanical Engineering
Indian Institute Technology Bombay**

**Lecture-9
Technology to Solution Part-2**

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What are the issues

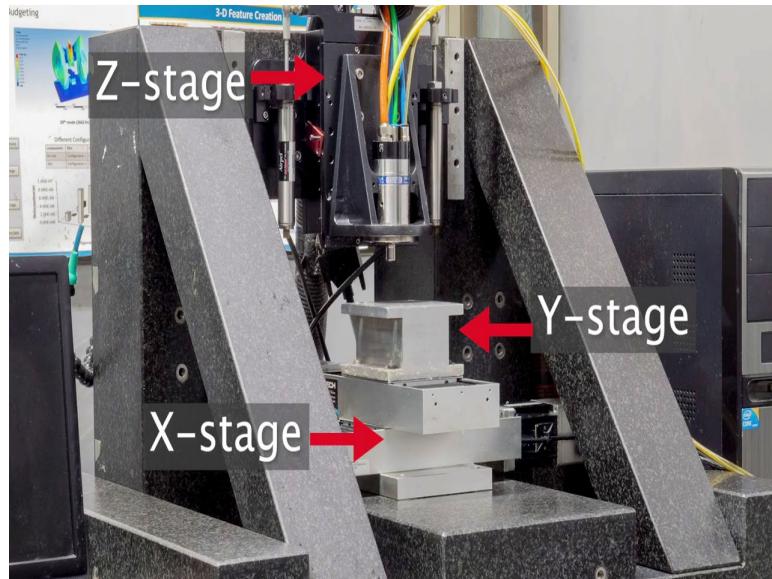
- Should not vibrate
- Need tool stiffness
- Need to optimize structure

The first one was that we do not want any vibration.

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So, we use the entire machine as granite, because granite has very good anti damping properties. Then what we did was, the tool stiffness is an issue that we talked about a little bit. you can go very, very high speeds to make sure that it cuts very small in one rotation. If you get a very high rotational speed you actually cut very, very little, the forces go down. And then I want very high percent precision so we basically have a very good structure, optimize the structure.

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And then I can have a high torque spindle and low-cost because I take a very good Z stage and XY stages that are actually precise but not super duper precise. When I am doing micro machining what happens is,

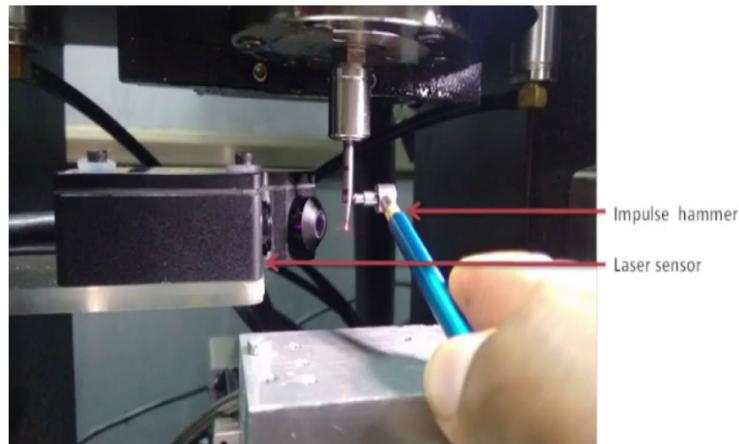
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How to find parameters such as

- Stiffness
- Damping ratio
- Natural frequency

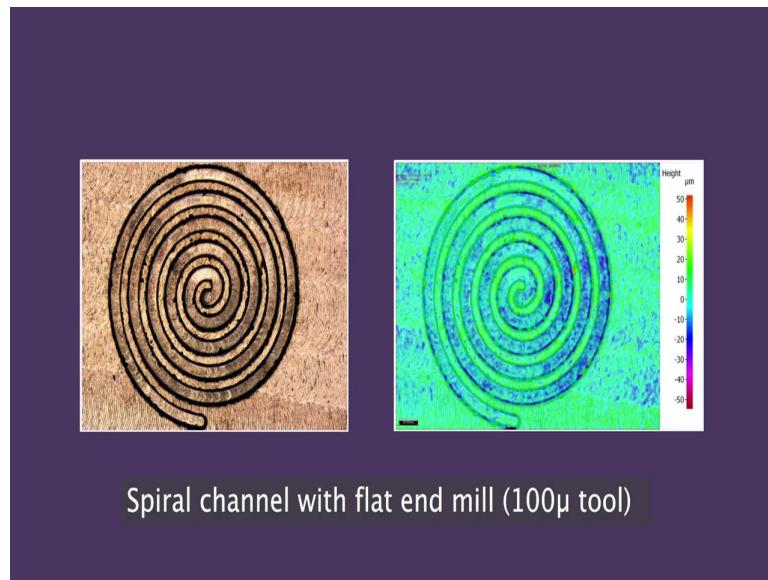
so, if somebody wants to say, the parameter of any, this stiffness, damping ratio or natural frequency, you know, how (do) they get those parameters? They actually excite the structure. So excitation is done either by a shaker to excite it or by a hammer. Take the hammer, hit it and then take something which will measure the vibration.

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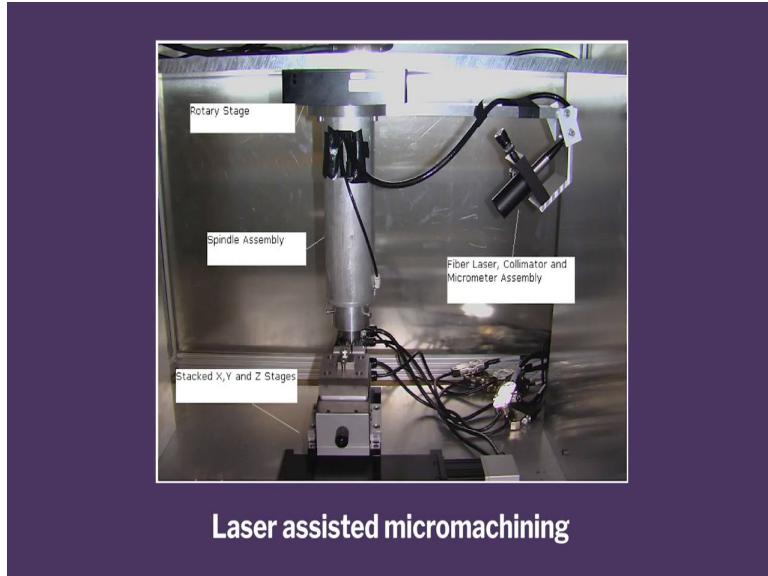
That can be an accelerometer which will measure the acceleration or a displacement sensor. We did not hit right at the end but the shank is thick, shank is 3mm the bottom is 100 micron. So, you do not hit the 100 micron because that will break, so what we did we hit at the shank, measure it at 100 micron. That is a challenge but has to be done.

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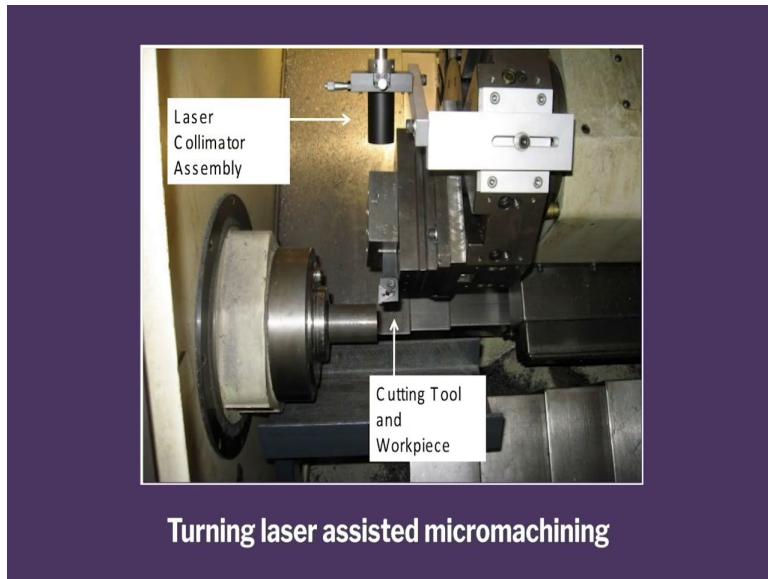
So, then we were able to create all these features. These are 100 micron channels 400 micron channels. Just to show what we can do with this. There are other things which we designed a machine, which would actually just take the laser, soften the material and then machine it. So that way the stiffness can be counted because now the material is softer.

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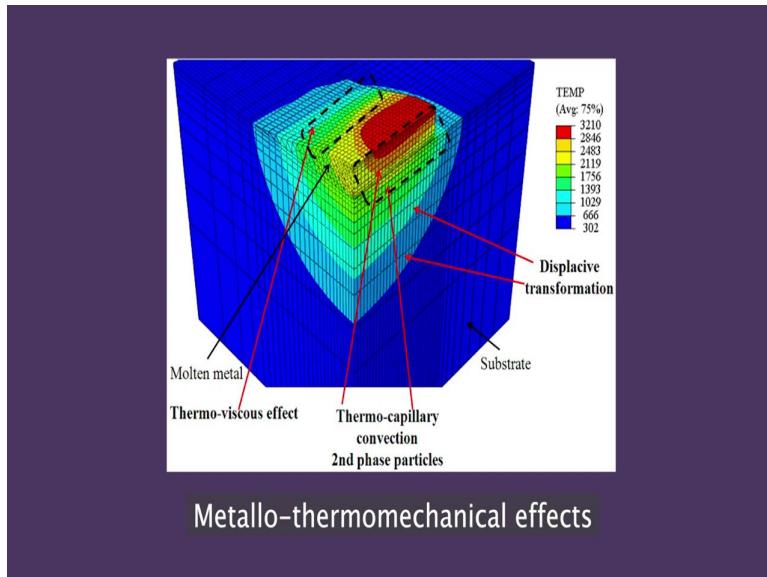
So, we did it in a milling setup.

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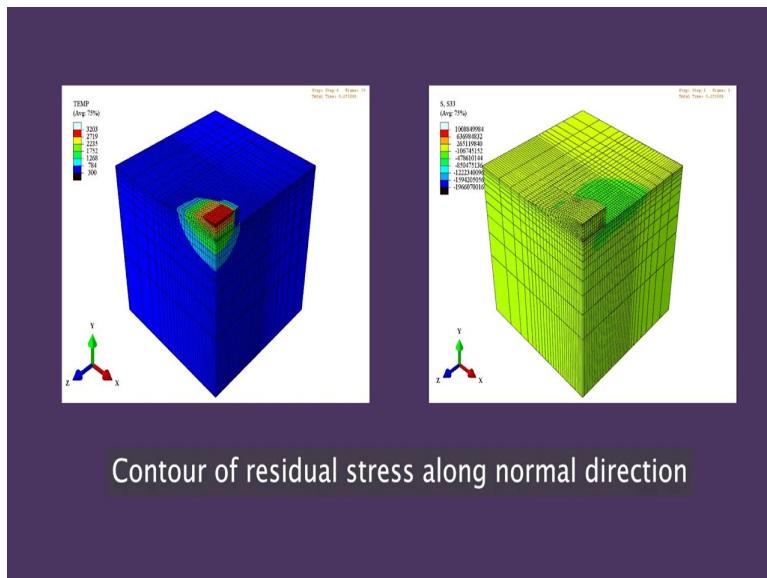
In a turning setup. Then I talked a little bit about additive manufacturing right, but the scientific issue with that is;

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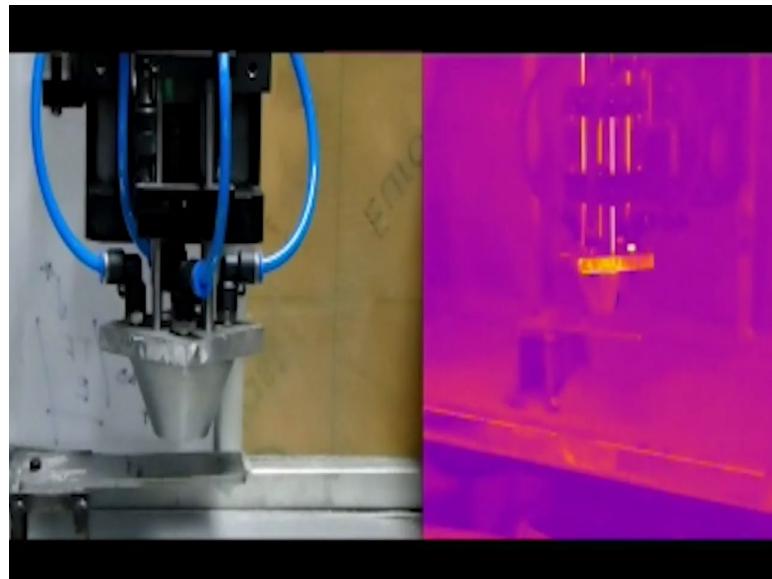
Because when you heat it, there is differential contraction, there are micro structural changes.

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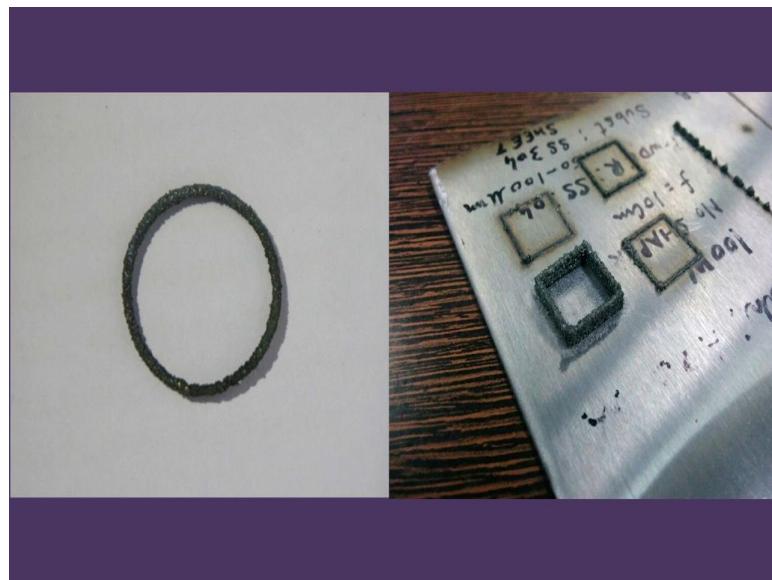
And those induce residual stresses. So, we understand that. And then we had a nice model and everything. Now I want to build one. Now I understand the process. I have papers. Now what brings me the most happiness is building stuff.

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So, there was one student, a good student who actually rigged the machine. He designed his own nozzle. This is a 3D printed one, in the left. Then he actually machined the entire nozzle. He built his own makeshift Powder Delivery system. See, it is in tatters but it works and then he build, he printed some rings, some boxes out of it.

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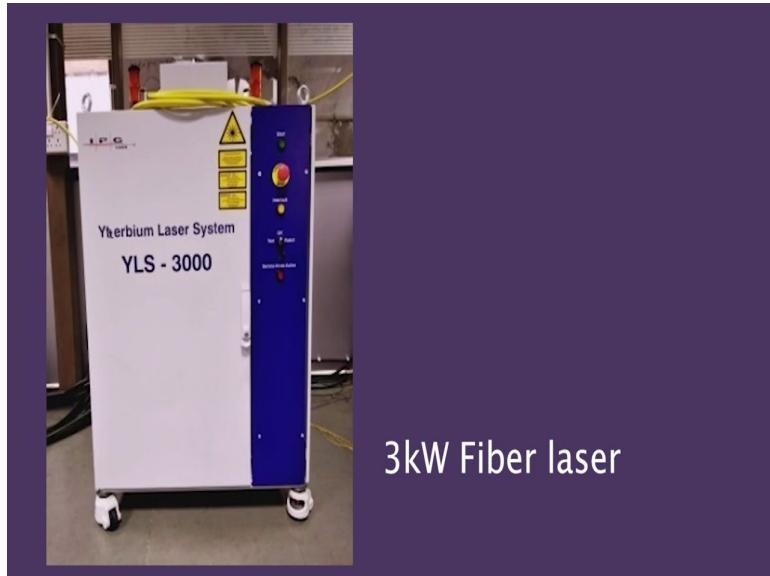
Then we showed these small contraptions and then went to DST, ‘Give us money’. They gave us few crores.

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And then the real job started, then we started building the real deal. Got a big heavy-duty robot, got a real cladding head. Cladding head basically means it supplies the material and the laser coaxially. So, this is what we are doing. We are actually doing this for Bharat Forge. We are taking the, we are depositing a very heavy, heavy hard material on top of their molds. So, tomorrow if they use this kind of additional layer the mold life will increase. So it is called hard facing.

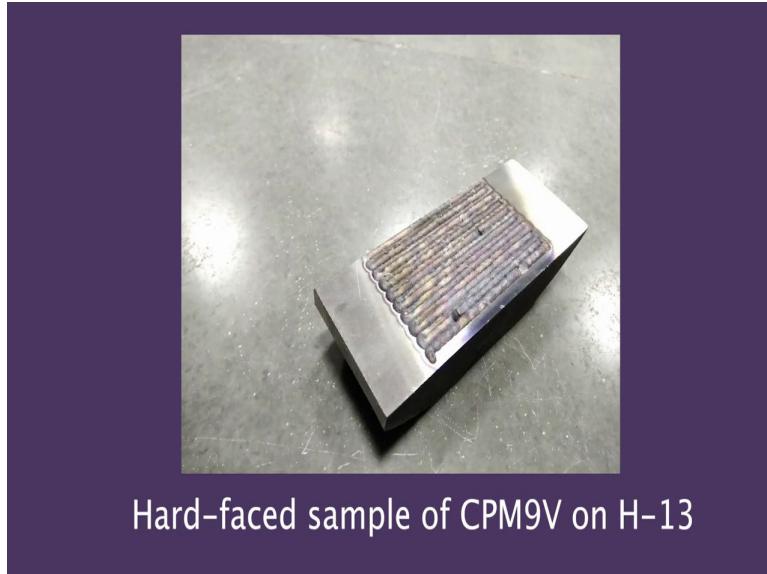
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3kW Fiber laser

Got a powerful laser, 3 kilowatt powerful laser.

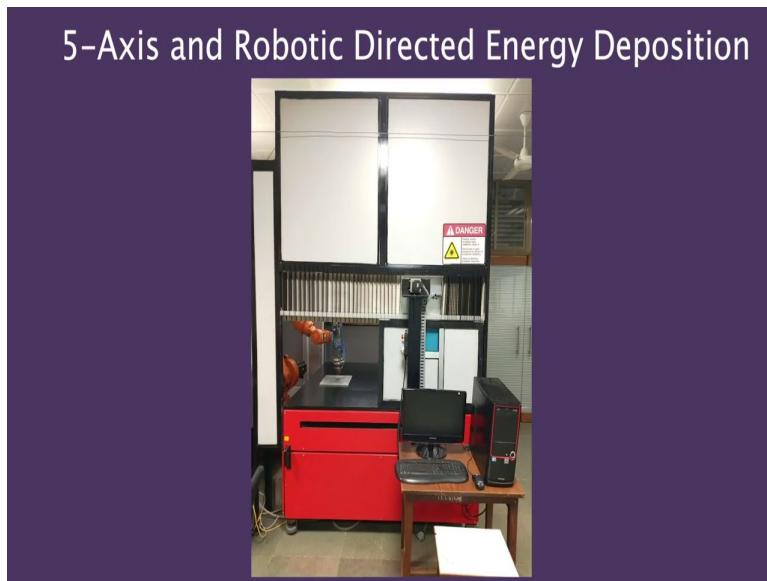
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Hard-faced sample of CPM9V on H-13

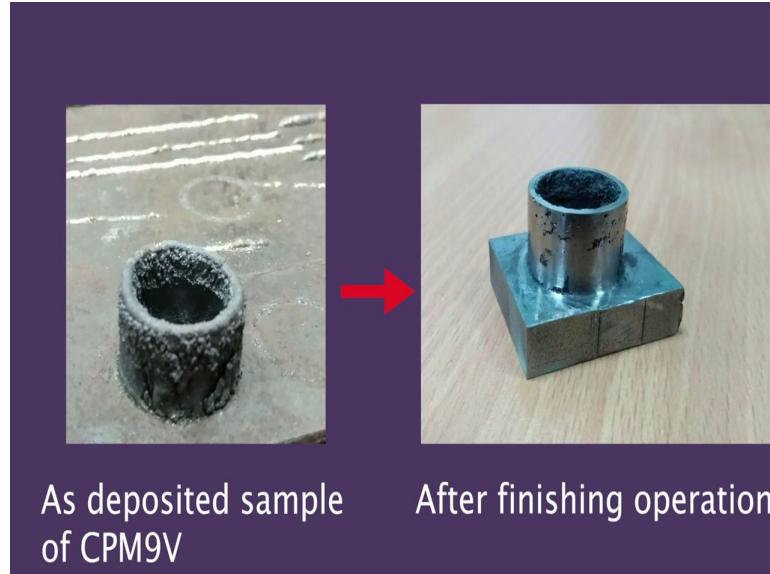
And then we printed something very nice.

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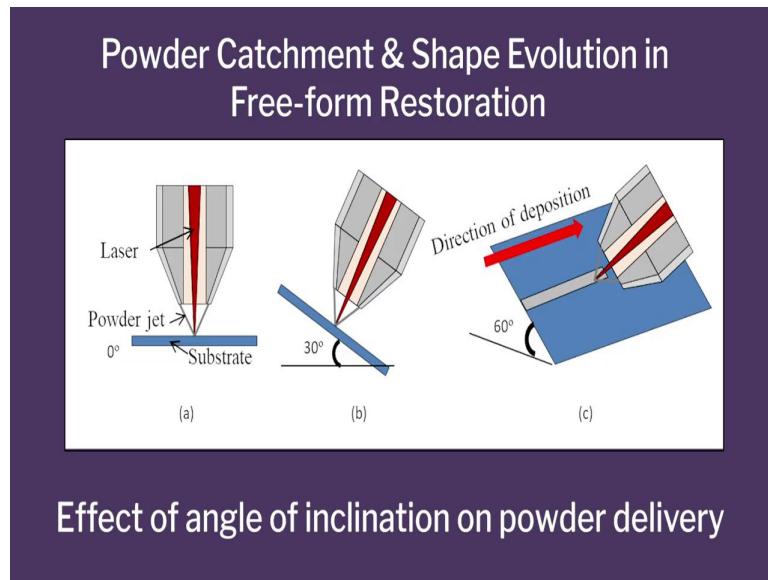
And improved the machine. Now we have 2 stations there. One is the robot. The other is a 5 axis system. Again we have designed this and got it built.

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So, if you go ahead you can polish it. It looked ugly right. If you polish it, clean it up, it comes out nice. So, it is 5 times normal steel strength. So, if I were to cut it I would have found a tool to cut it, it is so hard. So that is the beauty that this process can be a process where I can print super hard things which is not possible by using a machine.

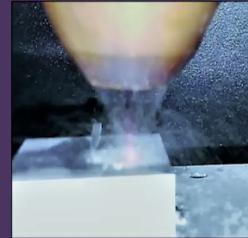
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And then we deposited it at different angles because if I do it like this I lose a lot of powder, because the powder gets skewed. We are trying to understand how powder comes because if I have to build in 3D configurations I need to know how the powder, how much powder actually, we call it Powder Catchment Efficiency.

(Refer Slide Time: 05:14)

Powder Catchment & Shape Evolution in Free-form Restoration



0° inclination



20° inclination



60° inclination

And how the material flows. So these are actually cross-sections after; so we did it at different angles, and if you do it really, really high angle, you actually lose most of the powder. On the bottom portion, that is what it shows. What a powder is lost. So that was the actual machine part of it. Now if I want to repair it I told you right we also need to scan the defect.

(Video start time: 05:40)

(Video End Time: 06:01)

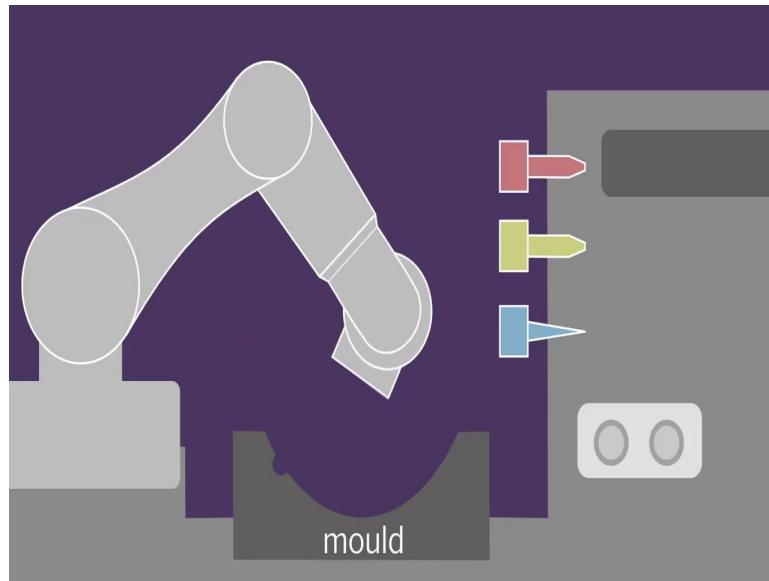
So, I will show you another video of scanning. So this is what we will propose to do. This will sit on the robot. This is just a dummy, easy to do but this will be done at a real product level. There will be a line scanner which will scan the entire entire product.

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And then build models like this. So right now I know there is a defect right in the center. These robots have accuracy of 50 microns, that is what they claim. It is much higher. The vendor claims that it is 50 micron resolution but I will still take it with a pinch of salt. Robots are not very precise things to do. If you want very precise then you will have to do something (like) what I did with the ball screw stages or linear motor stages. What I have built on the Micro Machining Center.

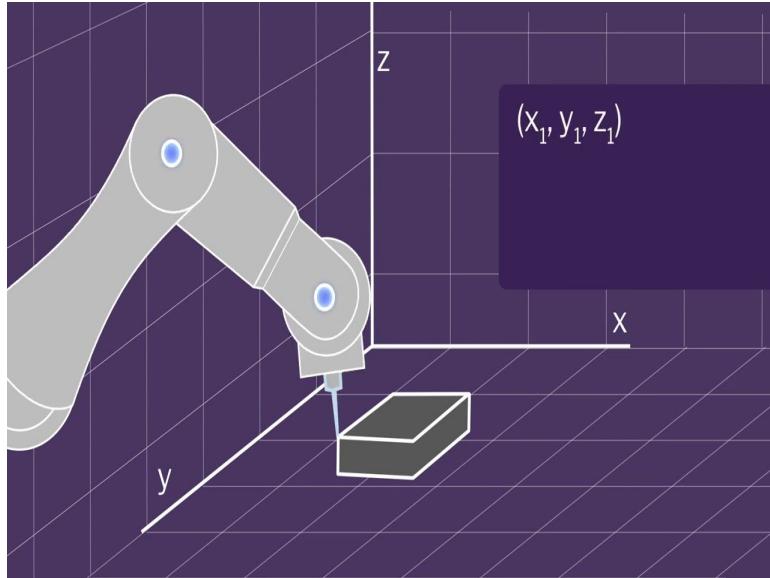
Those are nanometric stages. So if you have to (be) precise, then you will have to use a different set of kinematics. Robot is not a, it is very flexible but it does not have the same accuracy which you have in a gantry based system.

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So, eventually our dream is that there will be stations. The robot will go ahead and it will pick, first the scanner, scan it, place the scanner at the holder. Then go pick the printing head, print it. There will be a finishing tool, post deposition you will finish it, keep the thing back. Then take the inspection head, inspect it. So, that is our final dream, totally autonomous, that is our dream. When we make one we will sell one, but that is our final dream that it should be totally automated.

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Scanning is not 2D, it is a line scanner, but this line scanner is in space. So I have the data of where these lines lie, right? Where these lines lie in (3D) space. So, this line would give me, but this line, every line has some XYZ of the robot, I can combine all that data. I can get the data from the robot, get the data from the line scanner and create a 3D map of it. So, that is what the student does, the machine which I was talking about, the Vent Cleaning Machine which I want to showcase today.

This is how they do it, in the shop floor. So, he can do in less than a second, one hole he does it. We were doing 1.6 seconds, our machine was doing it in 1.6 seconds. We could do faster. I told him I can program my laser to move faster but then what will happen, all my optics will go away because of the inertial forces. Because if I do very fast there would be acceleration right, and these acceleration will exert forces on my optics and everything.

But then, a lot of the time what happens is the drill breaks. So this is the problem, that if the drill breaks then, and it goes into the tire. So you screw up one tire but the OEMs will return everything. Because OEMs, if you know, I do not know how many people know, how auto industry works. The only people who gets crushed is the tyre 1 tyre 2 supplier. Cars are getting cheaper by the day and the only people whose profits go down is the supplier of the OEM. OEM does not reduce its margin.

So if you buy a tire in the margin of 2500 rupees, the OEM buys it for 1000 rupees. That is the price but they still sell it to OEM because they want their tyres to go into Renault or Maruthi.

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Quality of tyres were not consistent due to metal leftovers from vent cleaning

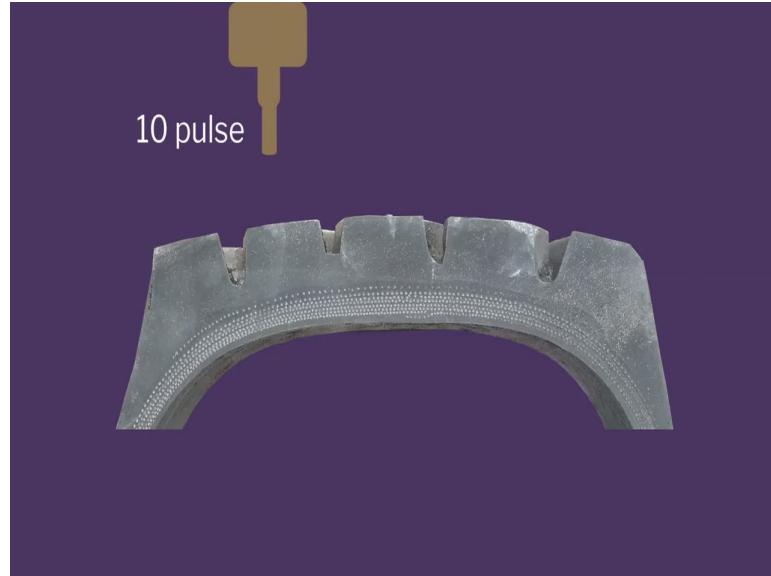
Cleaning Drill bit can break

Potentially hazardous as tyres can burst

So, quality of tyres were not considered after metal leftovers in the vent cleaning. Cleaning drill bit can be dangerous and potentially hazardous as tyres can burst. right? So, that is how they walked into the lab and said that ‘do it’. So, I asked them first thing is you just send me all these clogged bolts and I will play with it. So, we got those molds in the lab. One of the students came and he fired the lasers. Is it getting cleaned or not? So, that was the first step. We said it is getting cleaned.

We saw, we observed, it was getting cleaned. Then I said, ‘Ok, why don't we clean it with the air jet?’ . So, we put up an air jet and cleaned it. Gotten even better. Then they said, let us try nitrogen. They tried nitrogen. Is it improving? Try oxygen. Is it improving? So, nitrogen, oxygen and air did not make much of a difference. So, I said Ok, it does not matter, you do not require an inert gas to improve the efficiency. That was the fundamental idea which,

so people do a lot of experimentation when they sit in the lab. And then they said that how do we correlate how much, how many pulses we need? So, they took a tire piece, kept on firing lasers on it and said ‘How much deep it goes?’



So, they basically did a test by making holes in an actual tyre. They took a tyre and they kept on firing 10 pulses, 20 pulses, 50 pulses, different pulse energies because I needed to know what parameters are required.

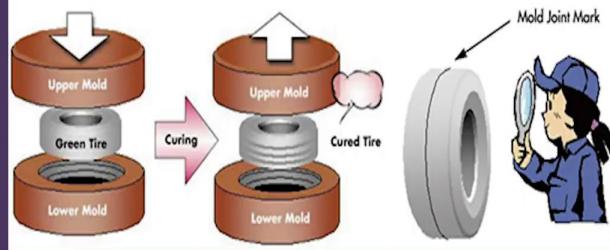
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So, this is how the tyre building machines look. This is an actual factory shop. So, this is the final process of making the tyre. First they just make a drum and then they make the side wall. This is a final operation where the side wall is already made.

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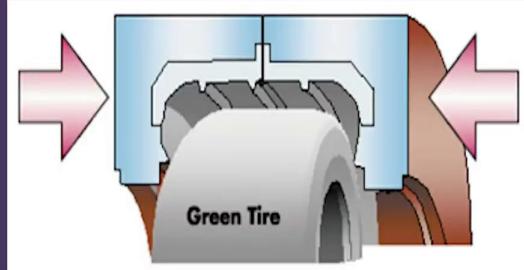
Building of Prototype



So, prototype building, what we did was, this is a two-piece mold. There will be one piece at the bottom and one piece at the top.

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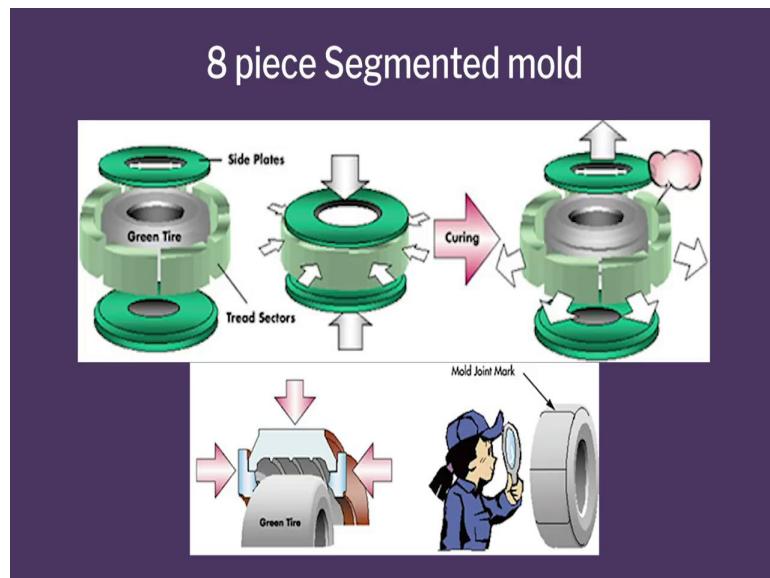
Building of Prototype



It takes something called a green tire which is not cured yet. It is called a, pre shaped tire is there with no treads or anything. It will come into the mould, all the treads, all the features which you see the tyre comes in the tyre mold. They will take steam and they use the steam to heat it up and hold at certain temperature and the temperature tolerances are very high. The entire thing should have few degrees, one or two degrees, within 2 or 3 degrees to make sure that the difference is not very high. Otherwise the quality will be compromised.

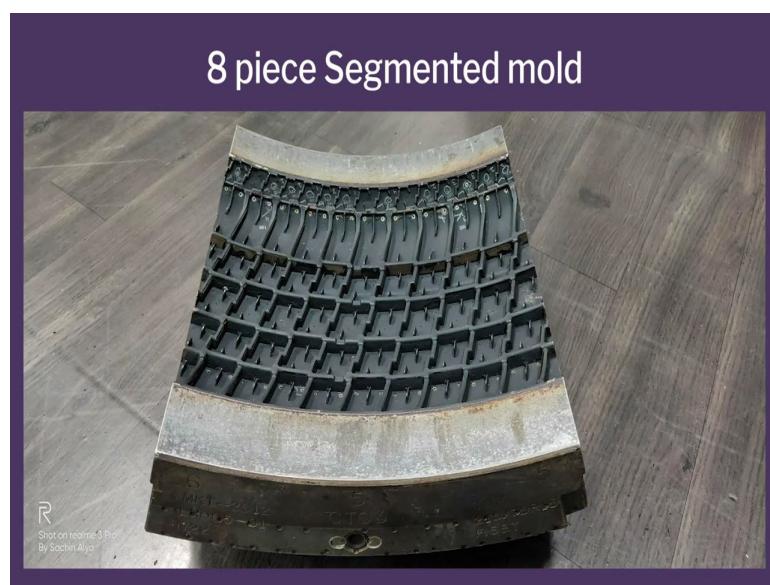
So, they want us to do another project now. They want an induction heating based system for curing the mold, but if I do something like induction heating, there is a gradient. So, they actually want us to redesign the entire thing. So we will said that we will actually reengineer the induction coil design. We will do some physics based modeling to figure out what would be optimal coil design and then do a conduction study of the mold, and then make sure that we design the mold with a combination of studies and some control.

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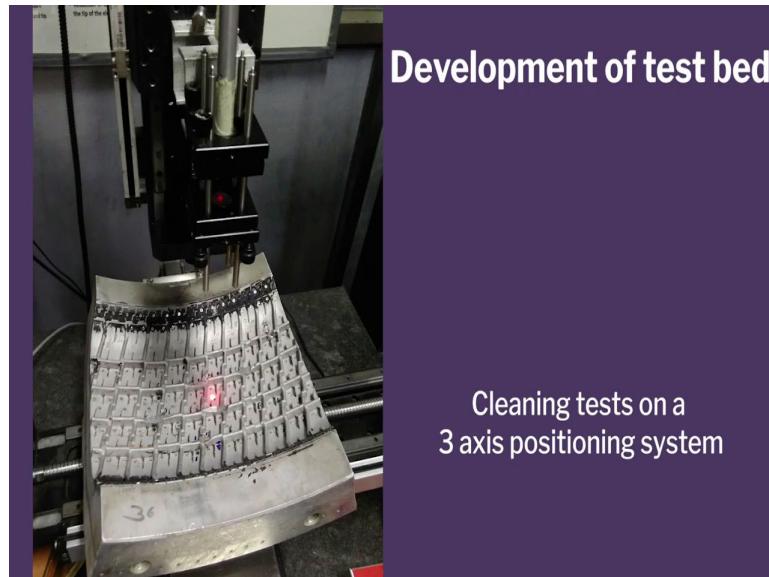
So, these are 8 piece molds. It is an 8 segment molds, made of aluminum.

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So, those are assembled and you see the vents will be somewhere here. There are all these vents are there. These are the vents which would have to be cleaned.

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Now the ultimate test bed is, initially I did not have the position to, position accurately, right? So, we would do the alignment by, the usual degree, you see it is right at the normal vector is there. So, we did not have a robot or you did not have a positioning system of 5 axis, right? So, we managed to do it using some tilting, something like that and then trying to make sure of that. Our idea was just to see the proof of concept, whether it is cleaning or not and then get to the kinematics of it.

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So, we did some experiments. This is the very first few experiments that we did. The first one we needed with the Continuous Wire Beam Laser (CW). CW laser is not the right tool because with a pulsed laser I get a lot more variables. I can do a number of cycles, I can give a lot more energy in small times, I can ablate the material very fast. So then we switched from CW to Nano-Second Pulse Lasers and the Nano-Second Pulse Lasers are much cheaper, 1.5 lakhs, and this 20 watt is continuous power, peak power can be 20 kilowatts.

So, it is actually, the peak power in Nano-Sseconds, if you see because 20 watt is the average power. If I keep it on for only a few Nano-Seconds, 100 nanosecond, 20 nanoseconds, the peak power is very high. It is actually in kilowatts.

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Need more than 3 axis for appropriate positioning

Laser Vent Cleaning system: Challenges

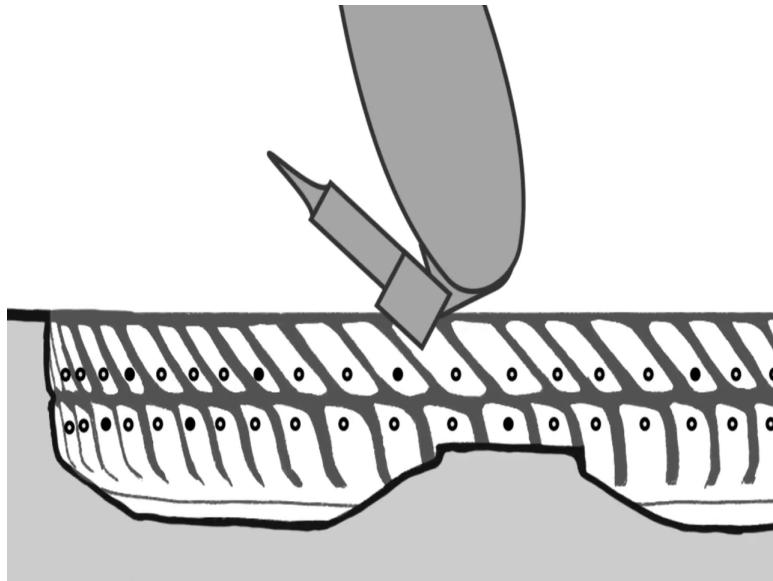
Curvature of the mold does not allow for the use of standard **3-axis** positioning system

3 Axis system
Mold
Not concentric with vent axis

6 Axis system
Mold
Concentric with vent axis

So that was the basic thing that 3axis pointing system does not serve the purpose, because I need to be normal to the surface. Whatever the surface is, I need a normal vector to the surface. So, I need a flexible position system, preferably a 5 or 6 axis poisoning system.

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So, that is how we built a, we zeroed in on a robot. So this is just the kinematics now, right? I need to be normal to the surface. But the primary challenge is how do I know where the normal is? That is a bigger challenge, right? and now I know I can position it. I have a machine to do it and I can clean it. What do I do, how do I know where the normal lies? So, a robot can do two things. I can teach a robot. The simplest would be I go ahead and teach, this is one, and this one, and teach one mold completely.

And it records all the locations and goes and fires there. That is the easiest way to do and the stupidest way to do. Because if I move it here, everything is gone.

Student: The position of the holes everywhere is the same?

Sir: Ideally, so they have drilled more holes. And the thing is the moment, if I train it, right, I need to either make a very good fixture or a registration system to make sure that every time it knows where exactly it is, where the zero is.

I move a little bit, everything is gone. This is the first robot CEAT got actually. Before that they have never seen a robot. And that is one of the bigger companies in the country. You teach the robot and then we will give you a registration algorithm. So, you will put some markers in every mold you get those markers right and then transform whatever data you had with respect to those markers. Every time you load, register the thing.

A month later they said, 'Why don't you build us the detection system?' After taking the machine. We showed them, trained them, we showed the registration thing, gave them the machine and said why don't you build it. And they said give it in three months. I said look, three months, I think nothing can be done. I cannot even put a purchase order to build anything. So, you know what, my student has a company, he will build it for you.

So, two months later they come back again. 'Why don't you, you are right, why donot you build this, build us the software for that'.

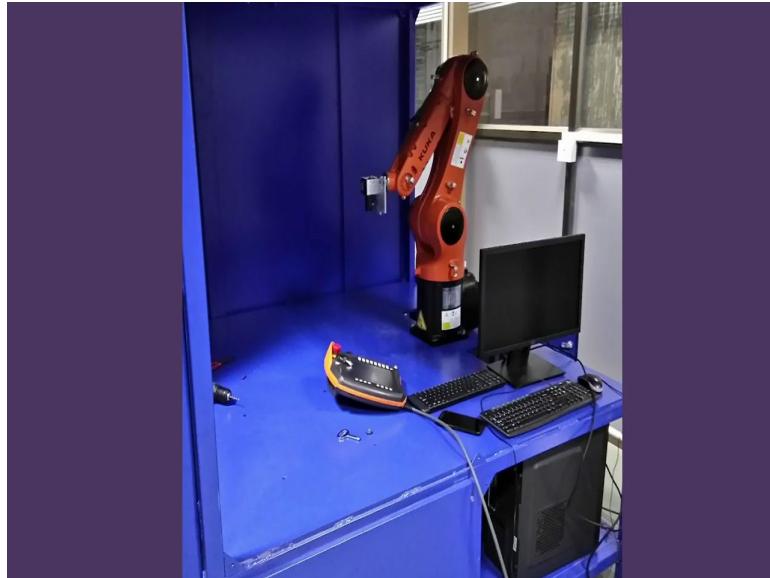
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So, we actually built a software which detects the holes automatically. It has an algorithm built in to identify where the molds are, so it is a camera system and it has also some sensors. So, it knows the location, so it knows where the normal lies. This is the Vent Detection System. We actually built a software, a vision based software for that. And identifies the holes and then goes and fires. So it records the data of the holes and it goes and fires it. So that was a second iteration.

(Video End Time: 16:40)

So, you understand what the problem was that you need to position it right. So we use the robot for that because we could not build a, right now we have, we actually have a 5 way system so we can use that plate form, for Vent Cleaning System.

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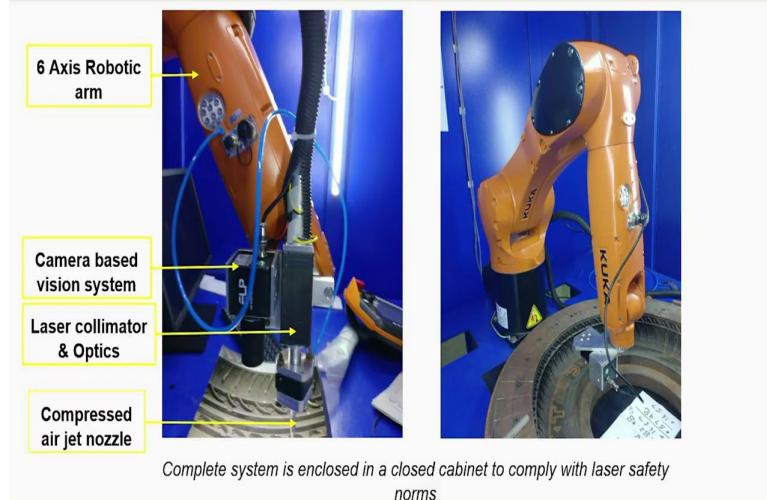
So, now this is how we built it. We actually designed an enclosure. Mounted the robot on that enclosure. Did all the electrical subsystems, PLC controls because the laser, the robot, the air supply, the camera everything has to be on one platform. This is how it looked and then we gave a nice window to do that.

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This is how the machine looked. Even all the, all the electric lighting was also, we did it.

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Laser Vent Cleaning : System parts



So, these are the main components here. The robotic arm, the camera, the laser collimator and the compressed air jet. So, there is a solenoid valve for the air jet also. The air jet, yes, air jet, with this is ablated, brings out debris, this debris gets blown out. So, you actually need an air jet to blow the debris away, what you have ablated.

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View from the debugging vision system



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Laser Vent Cleaning : Features

Laser: 75W pulsed fibre laser

Robot: Six axis KUKA Agilus

Compressed air jet to assist cleaning

Camera based targeting and point recording system

So, we use a 75 watt Pulsed Fiber Laser, robot, compressed laser, and a camera. So, this was the entire thing, entire components which were there.

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**Point recording for a
2 piece mould**

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Laser Vent Cleaning system: Training at IIT Bombay



So, this is the final, finally those guys came. We trained them. This is how the lab looked before. So typically what happens is, these lasers have 1.1 milli joule pulse energy. So, the power which it will give you is 1.1 milli joule for 150 or 180 nanosecond. So, you can do the math 1.5 milli joule divided by 150 nanosecond. What comes out of, it should be close to 20 kilowatts or so. Give or take if you do the math. So, this can do 100 kilohertz frequency.

So, it can do very fast frequencies. Otherwise what happens is if frequency is very low then I will not be able to do it very fast. So, the pulsing frequency is very high.

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And then we also, we are trying to develop in press cleaning for the mold. No, not the vent, not that deep vent cleaning but just the mold cleaning.

(Video Start Time: 18:58)

See. There is a line laser based thing with the Galvo scanner and it will clean it. So right now it is a very cheap laser. that is why the cleaning quality is not up to satisfaction because as I said, the laser and the Galvo cost me 1.2 lakhs the student went and bought from their own money. And they build a lot of toys with that. So, see there it will clean. It comes out pretty clean. So, actual laser cleaning applications require a much higher per pulse. So, right now I have 1.2 milli joules. Ideally, I would require 1 joule.

(Video End Time: 19:39)

But 1.2 milli joule cost me 1.5 lakh rupees when one joule cost me 114,000 dollars. Do the math and it \$114,000 is what 75 lakhs plus as these days, yesterday it was like 71 or 72 (rupees) I do not know, it is again skyrocketed, 71 something, so you do the math plus, 25% loading if it comes to India. And here I just go and buy, actually it was not one, for 1.2 lakhs they just dragged everything, with the laser, controller, scanner, Galvo scanner, F-theta lens, which is actually doing some cleaning.

So that is the thing. But if you really want to do good work, it costs money, but then some compromise if you do you can actually do it really cheap. That is the moral of the story. I want to give you, that if you are smart enough and if you understand little bit you can actually do a few things at a much, much cheaper price. But again, if you really want to do it good. So a German laser cleaning company says that do not contact if we have anything less than \$200,000 budget. Do not even talk to us.

It actually says on its website. Laser Cleaning is not cheap and this is what we counter. It has to be chap. Otherwise who will buy it right. So, any questions I think, I think we are coming to close on this topic.

Student: Sir, there are no poisonous fumes or anything?

Sir: That is a good question. You actually need a scrubber here, there will be fumes. So there are systems where you can have a scrubbing mechanism that we can make. But it is a very good point, if you really want to have a good product, if I want to sell it in a European country, I need a scrubber here.

So there is a very simple way to do it. What you do is you actually take a heavy gas and scrub it from the bottom. So, you take a heavy gas which will actually take all the fumes and you can extract it from the bottom. So, we can actually design something like that. I have some ideas to do that.

Student: Argon?

Sir: Probably argon you can do. Whatever is slightly heavier than the nitrogen because air *se heavy hona chahiye* (should be heavier than air). If it is heavier than air you can actually scrub it from the bottom. That is the typical, safest way to do it.

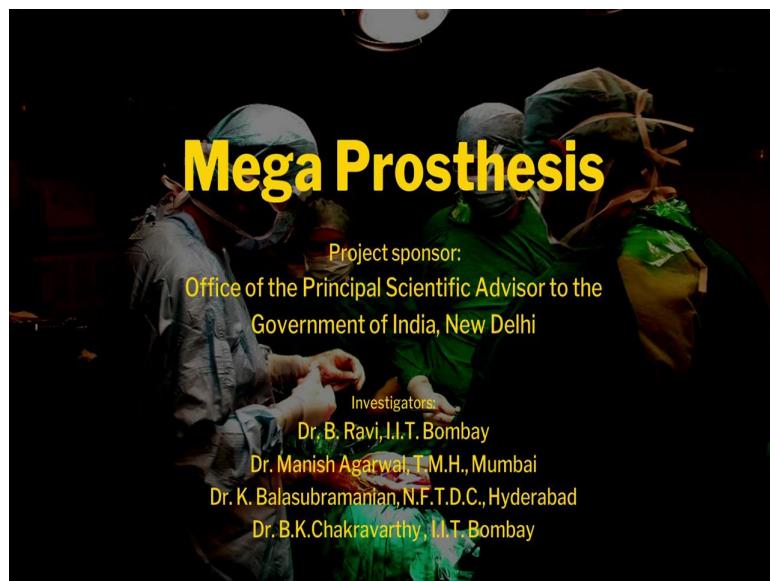
Design, Technology and Innovation
Prof. B.Ravi
Prof. B. K. Chakravarthy
IDC School of Design
Indian Institute Technology Bombay

Lecture-10
A Collaborative Excellence

Hello, all of you. I am extremely glad today to show you one wonderful case study. A collaborative innovation, across multiple departments, across multiple agencies and across multiple organisations. So, this is one wonderful case study where we can learn the design which does not necessarily need to happen with designers, even surgeons can design, professors can design, you know, manufacturers can design, right? We saw that happening earlier.

So, where there is design, there is research and technology, we only talk about technology in our course, but also there is research, right? Ahead of technology there is research which comes and embeds into technology from research your technology, and technology to application, right? All those things happen. And of course, there is innovation where the major hallmark of innovation is that it has to reach the people at large then only innovation is said to have happened.

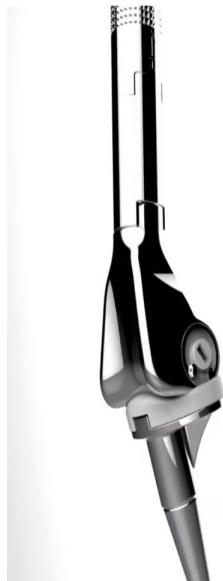
Otherwise we say that it is just an innovative idea or innovative research or innovative technology. So, those are the three important aspects which keep happening.



This Mega Prosthesis is a knee implant for children who are suffering from cancer in the knee and here, for example, if you do not have this mega prosthesis, the doctors would have to amputate the leg. This is a very, very interesting, sort of project, I am very fortunate that I was not the core team, but I will support team here, in the innovation, where I was working with the core team of professors, and doctors, and manufacturers where I would invite Prof. B. Ravi later on to show you how this whole journey unfolded.

So, right now just leapfrog directly into the, into the activity. Let me show you this film which completely captures this complete scenario so that you understand the complete scenario and then Prof. Ravi will come and talk to you about what happened behind this, how much of research happened, how many students and professors worked on it, what type of implementation happened and currently where it is. So till that stage we will have a B. Ravi from Mechanical engineering, come and explain it to you.

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T K P
Total Knee Prosthesis
A Collaborative Endeavour

(Video Start Time: 02:38)

(Video End Time: 08:13)

Hope you liked the movie? Lots of questions in your minds? Can I have one or more questions to know where you are thinking? **(Student Professor Conversation Begins: 08:20)**

Student 1: Sir, as it is made for children, and you are saying the life (of the prosthesis) is 10 years, so as they (children) grow what happens to them?

Sir: what happens to them. OK

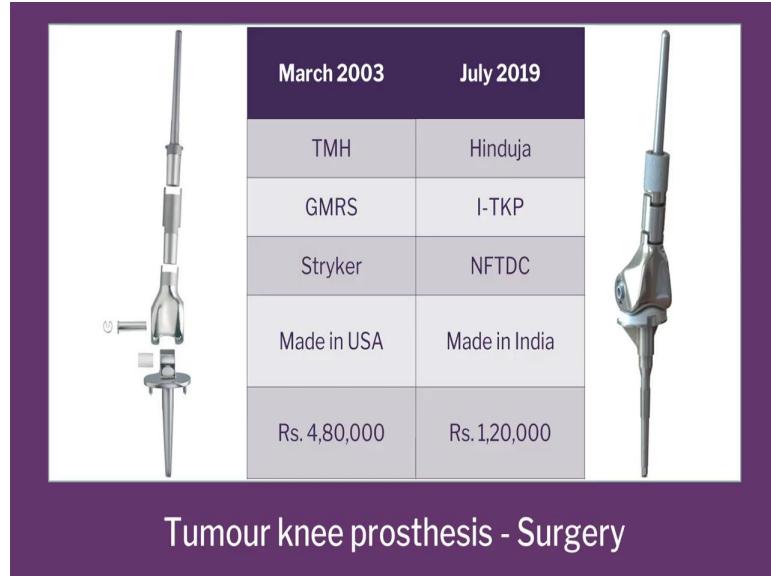
Student 2: Sir, so the dimensions, are they standard or is there, for every patient it could be different?

Sir: Good, I will answer that.

Sir: Yeah, I will answer that also.

Alright, so that was a trailer of the movie as you can see, and what I will do is fill in the dots, fill in the gaps, and tell you a little bit more about what happened, how it happened, who did what, when, where and so on.

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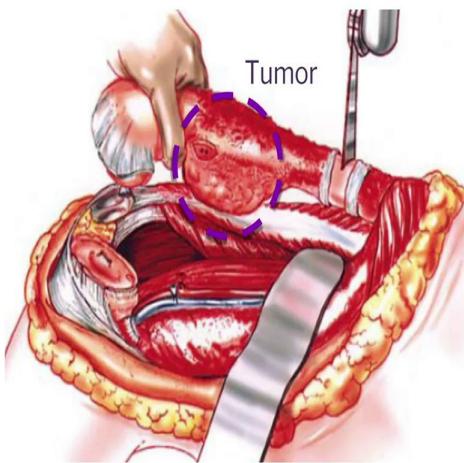
There are 2 implants which you can see in the picture. There is a big difference between the two. The first one, is an imported implant. And, it is about 4.8 Lakhs rupees as you can see. The second is what, the one which was developed in this project. One fourth the cost. But between them is a long story of about 13-14 years.

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The first picture which you see is an actual surgery happening for a boy, a 12-13 year old boy, who had bone cancer around the knee joint. Instead of amputating the leg, they opened the leg, removed the knee joint along with part of the bone and replaced that with a mechanical joint. Ok. So this is what happens.

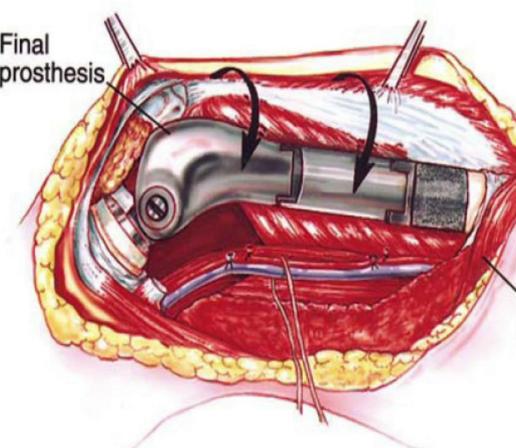
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Removal of knee joint with Tumor (with bone)

So, the picture, which is the bone, which is removed. You are cutting the part of the bone going out. This part is the tumor part. If you do not remove the bone along with the tumor, the tumor is going to spread throughout the body and metastasis, and then eventually all organs will be taken over by cancer. And then when you remove the bone along with the tumor, there will be a large gap left. That gap has to be filled back, that is why it is called as a Mega prosthesis

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Mega Prosthesis Knee joint

Unlike your arthritic knee joint which our grandparents did, which is just like a lining on the knee joint, this is like removing the knee joint and part of the bone, so we are replacing it with the large joint so that is why it's called a Mega prosthesis.

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So this doctor Manish Agrawal, he was at that point at Tata Memorial Hospital which is the largest cancer hospital in Asia. So, he would see these imported joints and see that they were very expensive.

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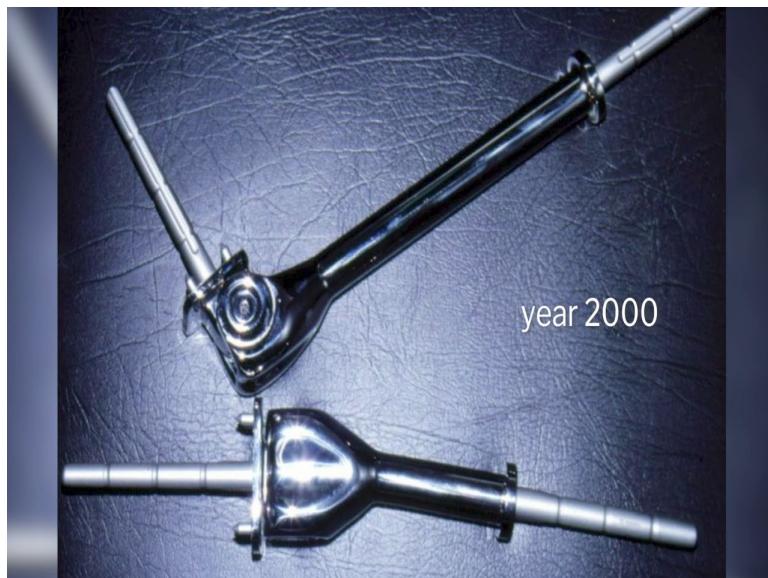
So he went to some local manufacturers who he knew to start manufacturing a very simple version of the whole thing.

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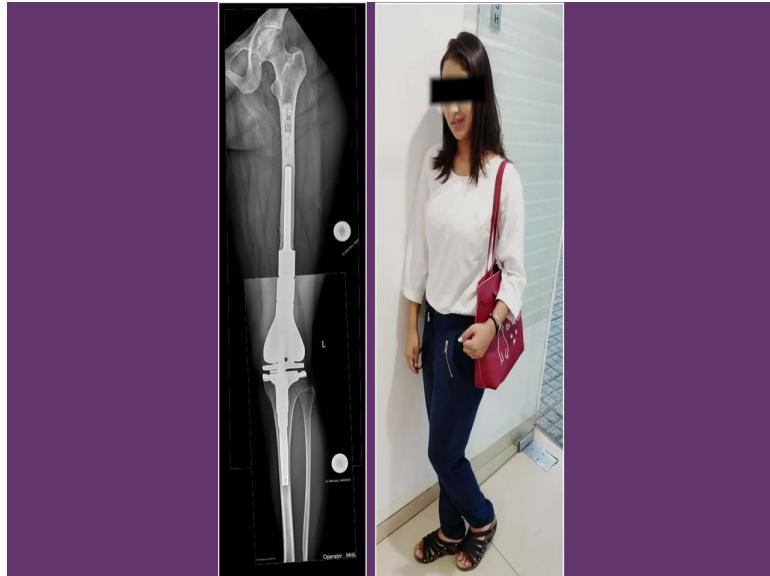
But with those cheap joints.

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He started benefiting a lot of patients who are otherwise very poor to afford the imported knee joints.

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If you can see this girl walking, you cannot even make out which leg that she got the operation done on, it is so very natural. She wanted to become a model. Eventually she became an air hostess. And as air hostesses do you know, they do all kinds of juggleries.

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(Video Start Time: 11:08)

(Video End Time: 11:17)

And you should come out at a very high speed and immediately stand up and so on. The high loads on the knee joint, natural or artificial, it has to be taken care of. So this doctor started going to this local manufacturer, started implanting those joints into the patients, at very low cost. Hardly it used to cost about 30 to 40,000 rupees.

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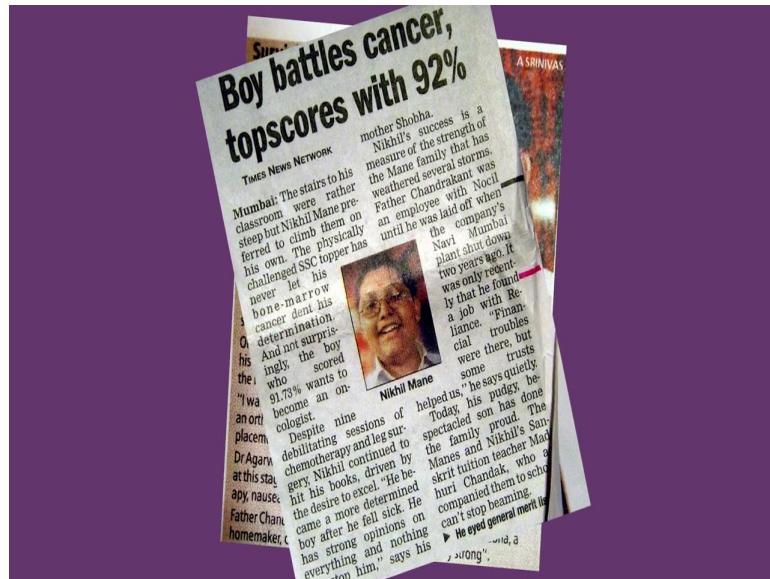


And slowly started improving the joint parts. So the patients were benefiting, joints were improving but only after sometime, you started getting some problems.

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First it accolades, the newspaper said, 'OK, something great is happening!', and this boy for example, not only topped his class in some categories and so, he wanted to become a doctor eventually.



But on the other hand, slowly over a period of 2, 3, 4, 5 years, failures started happening.

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Early Breakage

So, when we talked about failure and then I met him after the conference. He said these are breaking, or these are loosening. You can see the X-ray picture also, the stem is breaking.

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Early Failures - Metallosis

Or this is what is called metallosis, where because of this, not a great bio-friendly material, you know, some stainless steel is bio-inert but not necessarily bio-friendly. Eventually, if you do not use the right composition materials, your blood can get poisoned. And eventually infection and this can, this will actually need an amputation of the leg. There is nothing you can do about it afterwards. He also met Dr. Chidambaram in a conference, who was the Principal Scientific Advisor to the Government of India. And Dr. Chidambaram said, ‘Why don’t you come and talk to me and explain to me what you really need to do’.

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TKP Surgery by Dr. Manish Agarwal at TMH,
Mumbai

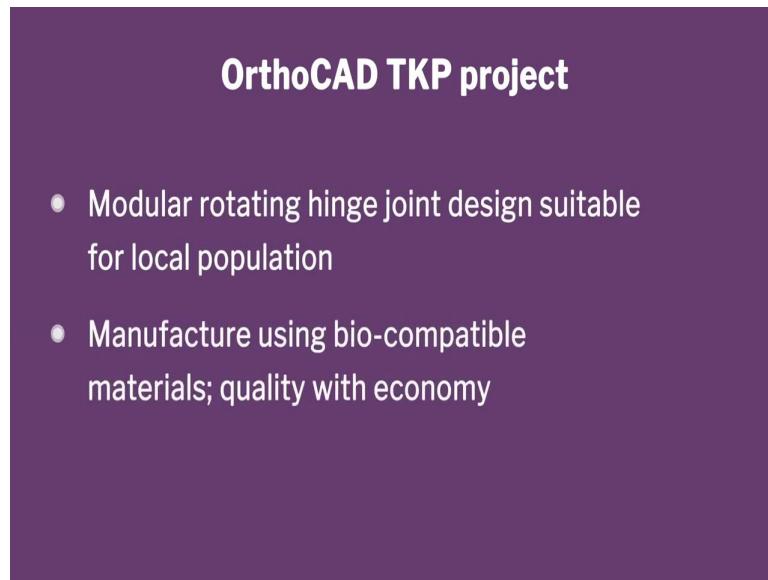
So I first of all saw the surgery, more carefully, understood the problem firsthand. OK? Then we all met Dr. Chidambaram and he said, ‘OK, I will give some funding to do some indigenous

development of this prosthetic implant'. So we started it off. It was a generous funding of about 5 crore rupees in 2006-2007 we started.

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And we said we will develop this Tumor knee prosthesis for children affected by bone cancer.

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The slide has a dark purple background. At the top center, the text "OrthoCAD TKP project" is written in white. Below this, there is a white horizontal bar containing two bullet points in white text:

- Modular rotating hinge joint design suitable for local population
- Manufacture using bio-compatible materials; quality with economy

And we also said, we will create a novel kind of hinge design, we will use biocompatible materials.

We said we will test the joints before putting in patients. Ok?

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OrthoCAD TKP project

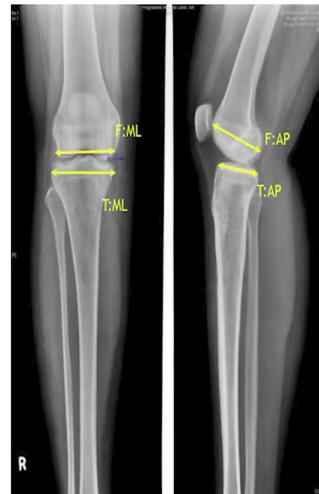
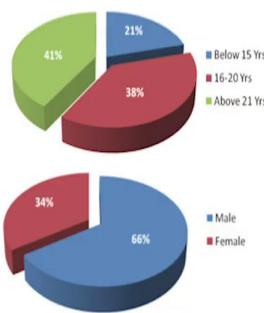
- Testing the knee prosthesis for fatigue and wear using knee simulator
- Surgical armamentarium for measurements, resection, implantation
- Virtual surgery software to select suitable parts, plan correct position.

We also said, we will create instruments to do the surgery properly and we will also try to do a software development to plan the surgery in advance. In other words, not just one product but also the entire system of things which you need to make sure that product actually goes into the patient successfully. Of course, we never promised that it will go into patients. We said we will develop everything that is necessary to be there.

So, one question was that, 'Is it suitable for Indian patients?' Because imported joints are made for those countries' patients, usually Americans, caucasian males and females and so on.

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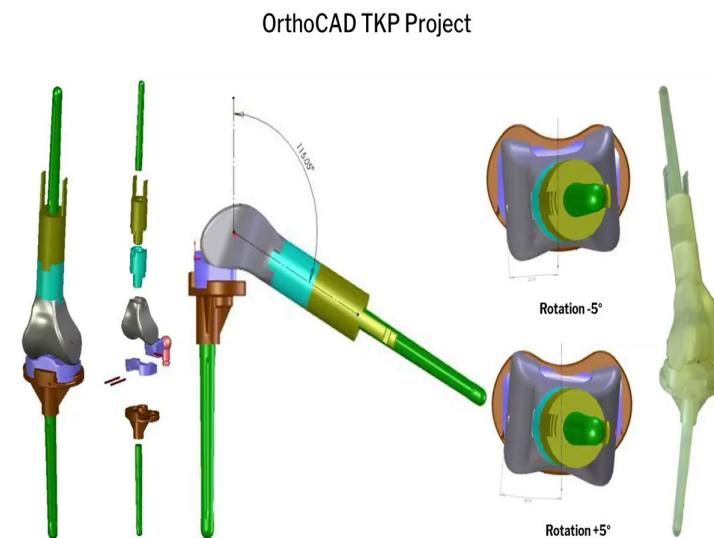
- 230 Indian patients
 - Measurements of healthy legs
 - Femur ML and AP
 - Tibia ML and AP
 - Bone dia: inner, outer
 - Valgus angle



So we went ahead to measure the dimensions on X-rays of hundreds of Indian patients to get to know what are our sizes, our standard sizes and then we clustered it to create a small, medium large size. Otherwise American small size is equal to our medium size. But again then the shape is not correct. You take that small and keep our medium it will be somewhere it overhangs, somewhere it under hangs and there is a problem with that.

So, we created the size and shape which is suitable for Indian population. Then we also said that it has to mimic the natural movement of the knee joint. Natural knee joint just doesn't move like this. There is also a slight twist in the other direction which prevents it from having shear stresses.

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So we put an extra rotation in the whole system. Also we did not want to copy the imported joints. So we had created our own methods of creating, giving those moments. So, it can be patented, otherwise it cannot be patented. You cannot copy something which is already patented by other countries.

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Alluminum Model

We built the aluminium models. We eventually had a 3D printer.

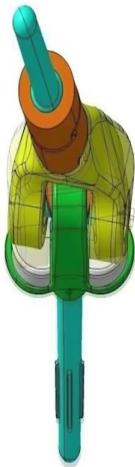
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3D Printed Model

So we built 3D printed models in plastic. Every time you print a model, you go back to the doctor, show it to him, he will make it move up and down and say, ‘Maybe this shape is not correct, do this like that’.

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Maybe this size is not correct, do like that, this moment is too much or too little'. So, every time they give a suggestion, you go back to the drawing board, modify that, create another model and go back to him. Do you have any clue how many times we made the modifications and built the models? It was 50 to 80. Eventually it became almost 80-90 changes. But every change, you know, is very painful.

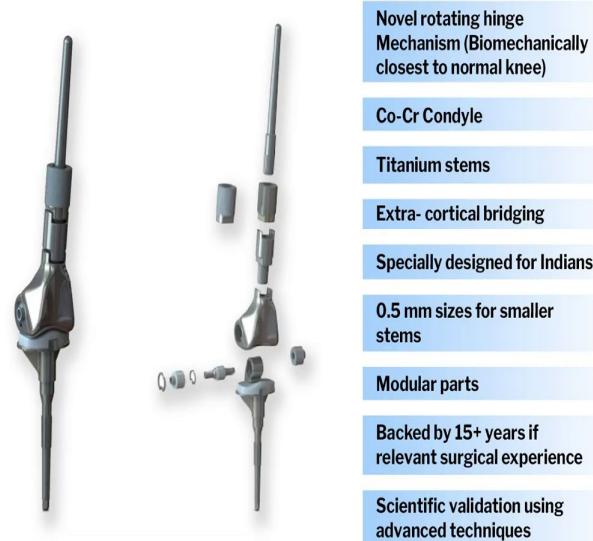
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And the doctors, what is there, they say that, 'This slightly more curved it should be', but the thing takes hours to change, model on CAD and then may be days to manufacture on a CNC machine.

So we started taking signatures saying, 'Ok, are you saying it is final from your side?' Lots of fun, of course, we had, but also a lot of pain we had. Now, eventually what happens is you cannot make a standard joint for every patient because every patient's size and shape is different, but also tumor is different and tumor location is different. So you need different prosthesis shapes entirely for different patients.

But then if you make a specific joint, only for the patient, it will take you days to manufacture, design and manufacture. And you won't even know if it is safe or not. We cannot do that either.

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So we took a middle path. We said we will make what is called as a modular joint. A joint which has a small, medium, large size of as you say the Condyle. The middle large part will have different diameters of the axis or the stems, which goes into the bone at the end, and it's all mix and match. You can take a large Condyle and a small stem or a small diameter, and we can put a mix and match. So you can literally have tens of thousands of combinations of whichever patient is there and i can always build something that will fit his size and shape.

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Then we went to the manufacturing partner which is NFTDC, Hyderabad. The director of that Dr. K. Balasubramanian.

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He came forward and said that we will give you all our resources, team knowledge and experience and of course machinery and equipment.

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3D Printing

And they put new equipment for manufacturing this design.

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So, we had CNC machines.

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CNC Machining

We had robotic polishing machines,

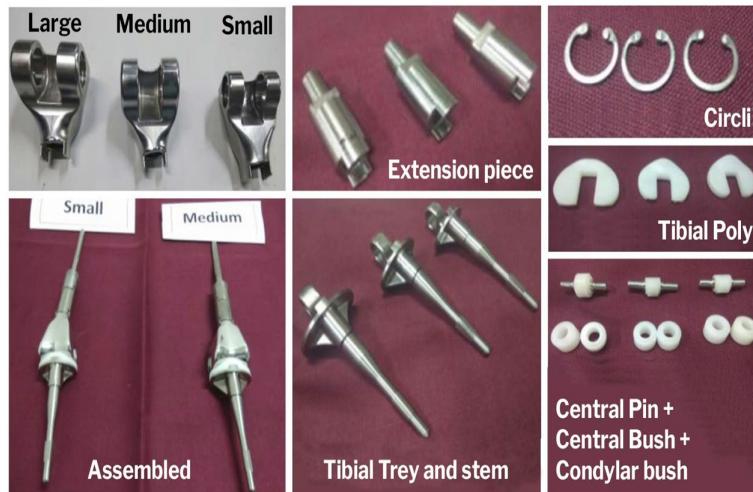
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Robotic Polishing

to polish the thing to mirror finish because when you have movement, metal to metal movement you want mirror finish then you have minimum fiction, minimum wear and tear.

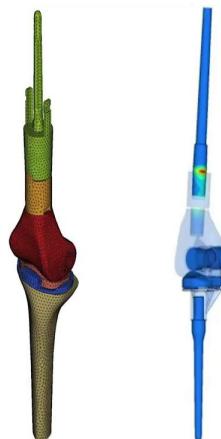
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TKP 2.4 Parts manufactured at NFTDC, Hyderabad

And then eventually we produced the first batch of those joints. Small, medium, large and different diameters, you can see the whole thing is about 10, 11 parts, which we can mix and match. The first batch came out. That was a big landmark for us. It took us about four years, three to four years before we got the first match. Now we cannot put this into the patient unless we are sure about its safety. So first what we did was to prove the safety on the computer itself, virtual testing. So we can do what is called as a FEA, Finite Element Analysis.

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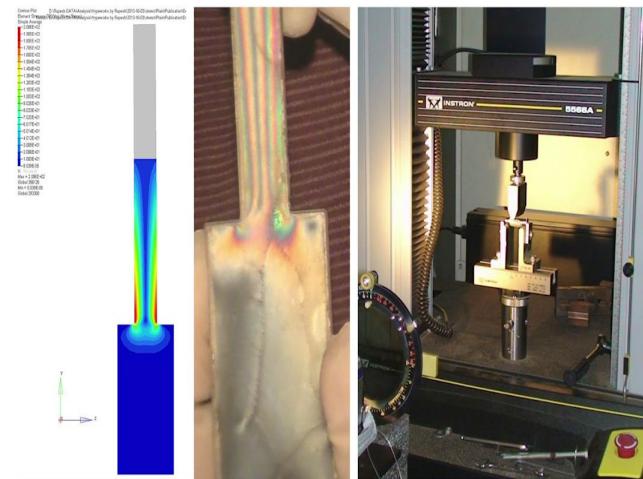


Virtual and experimental testing at IIT bombay

We can put virtual loads on to that and you can get any colour plot. Red is high stress and blue is low stress. So we can add material at high stress and remove material at low stress, so you can

optimize the size and shape. So it is low weight as well as it can take high stress. It is about a kg in weight.

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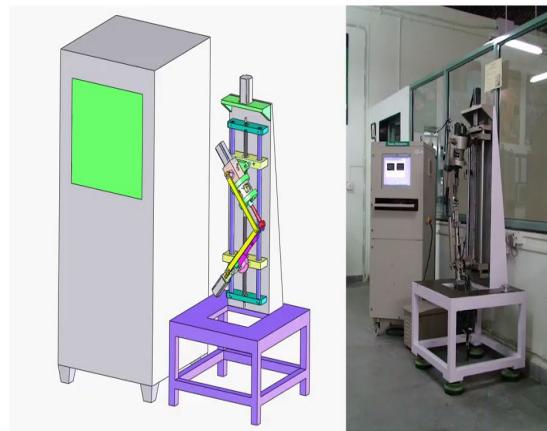


Physical stress testing

And then you need physical testing because doctors do not believe in pretty pictures produced in a computer. They say, 'Show me physical proof that it is safe'. So you load the thing on a, what is called as a UTM, Universal Testing Machine. Put the actual load on to that, and then see that it is actually not failing or breaking or so on. But doctors are still not happy. They said that you are putting a static load. What we want is, the patient actually walking, and jumping and things like that.

Let us say that your weight is 60 kgs. So each leg, you would think that the load taken by the leg by the joint is 30 kgs. It is not so. The dynamic load on a knee joint during walking is 2.6 times the body weight. It means if you are 60 kg weight, each leg takes $60 + 60 + 30$ that is like 150, 160kg weight. OK? That is doing normal walking. If you are doing jumping or things like that you can go 8 times. Stair climbing is, for example, 5 to 6 times bodyweight. Jumping can go upto 8-10 times of body weight. So take care of your knees. You can punish them now but will pay the price when you are old.

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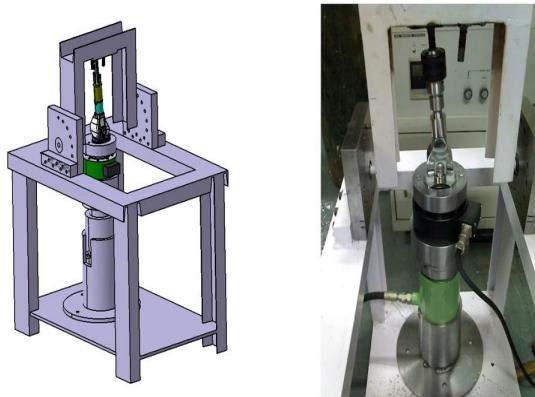


Fatigue & Wear Testing on Walking Machine

So, we built these machines to simulate the Dynamics movement of the knee joint. And then, typically, we walk for about 1 million, which is 10 lakh cycles per year. You want the joint to last for a few years but the testing itself takes a lot of time. We need to accelerate the testing and make every moment in about 2 seconds, one cycle in 2 seconds, it will at least take you 4-6 months to reach maybe 2 to 3 million cycles?

It will take you 1-2 years to cross 4 – 5 million cycles. So it takes a lot of time for testing. Our problem is that our machine started failing before the joint failed.

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Second generation machines developed by NFTDC

So we built another generation of the machines. This was built by NFTDC. They made a simpler but more robust machine. And on this machine our joints eventually went for a 10 million cycle, which is 1 crore. It is equivalent to 10 years of walking. So if something doesn't fail for 10 years, they know it is reasonably safe. Each cycle is about 2 seconds. So, if you calculate, and of course you need to give some rest. When you take it out maybe after a 1000 cycles, 10,000 cycles. Do some measurement. Put it under a microscope and see that it's not worn out and so on.

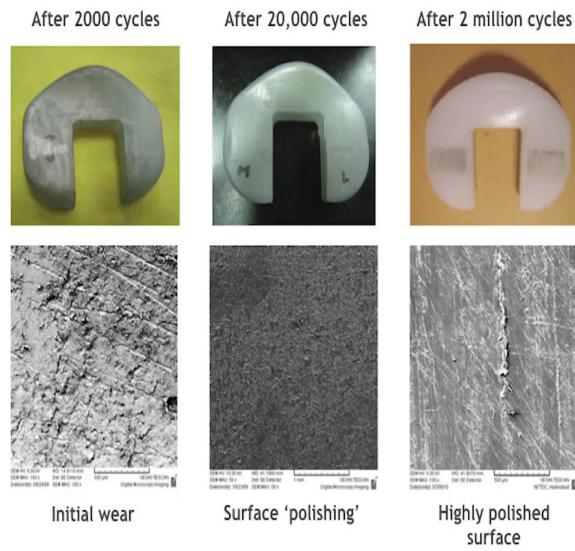
So, for us to reach that 1 crore cycles, it took us 4 years time.

Student: Sir, you said that there could be many combinations of all the parts more or less and, did you test all of those combinations?

Sir: Great question. Did you test all the combinations of all the sizes. No, it is not possible because again not enough time is there. You test the worst combination which is typically the smallest size because small sizes, if you put the same amount of load, punishing load, it will break easily. If the small one is safe you can assume that the larger one will automatically be safe. That is what we, that's the strategy we kept.

(Student Professor Conversation Begins: 20:59)

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So, this one which we showed the picture here, it's a polymer part. I did not mention to you the material of the joint. So, let me tell you that now. So, stainless steel is bio-inert. It is neither friendly nor is it an enemy. But if you want to buy a bio-friendly material, it is titanium. Titanium, if you

make it the right surface finish, the bone literally grows on the titanium parts and can grip it very nicely.

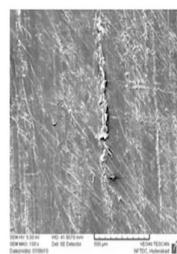
So, the stem portion which goes into the bone onto the joint here, not completely, because you anyway replace the joint, but if now you get onto the stem and grip it very nicely, so it will not fail so easily. So, the titanium stems we used. But titanium is very poor in wear. You have a moving part. When you have a moving part you have wear. So where you have wear, you cannot put titanium. So, what we do there is we put a cobalt-chromium-molybdenum alloy, which is a highly, very strong, very highly wear resistant material, but much more heavier than titanium.

But fortunately that does not go into the bone, titanium goes into the bone. So you use cobalt-chromium-moly alloy for where the movement is there. But, even if you make the cobalt chromium alloy for mirror finish, it is an under submicron finish, you can see your face into that, even if you do that still, nothing is a flat surface if you go under a microscope. So we don't want even that chance of wear and tear. So we put a polymer between the two metal parts. This is not ordinary polymer, it is Ultra High Molecular Weight Polyethylene. Very dense material.

And when you put poly, polymer in between, so the polymer is there, other side you have the cobalt chromium part, below also the other cobalt chromium part is there, and that movement has very, very low coefficient of friction. So it can go for a long time. That is the whole point.

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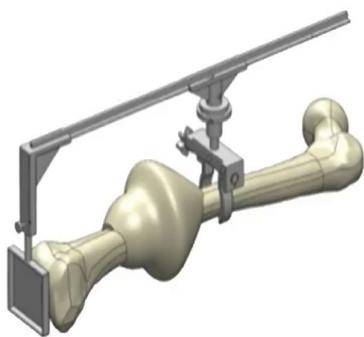
After 2 million cycles



Highly polished
surface

So what you see here is, for example, the wear and tear after maybe more than a million cycles, very little wear and tear. In fact it becomes very smooth. It becomes more smooth after some movement. So, of course, we made sure that the loads are not too much on the polymers, so a lot of small things have been taken care of in the beginning. Now, that is about the joint but then you have to use instruments to put the joint accurately in the human body. The joint may be great but surgery is not done properly and if the whole thing fails, my engineers will get blamed and you don't want that.

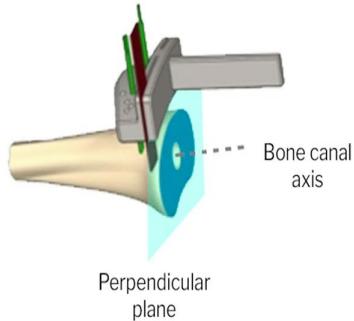
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Initial design of surgical instruments

So we want to make sure that the surgery is done properly. So, for you want to do an accurate cut of the tumor and also where the joint is going to enter the bone.

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Initial design of surgical instruments

For example, this surface has to be perfectly perpendicular to the bone canal. The bone canal is the hole in the bone. If the surface and the canal are not perpendicular, you will not get a proper biomechanical axis. You will make out the moment when the person walks, that is walking a little bit wobbly, not in a natural way. So, you have to get this right. So we created instruments to make sure that the cuts are perfectly done.

So this is of course for a joint, for, to put in the kids thing but the kid is continuing to grow, and grows drastically, there are two-three solutions for that. One is that if he grows by 1 or 2 centimeters, you can always account for that by putting a more heel in the shoe, that is a simpler solution. A more drastic solution is that if he grows beyond, lets say, 1 inch or 2 inch and shoes adjustment is not good enough. You have to take the thing out and put the bigger one, which is a very drastic solution. Ok.

But there is a third solution which is there, which is that, we put one component in the entire joint, which has the worm gear mechanism. And you can either put a screw from outside. Just a screw only, not take the entire joint out, and you can turn the screw and it kind of expands. Expandable prosthesis. But still you need to put a screw inside the body, and whenever you enter the human body, there is always a chance for infection.

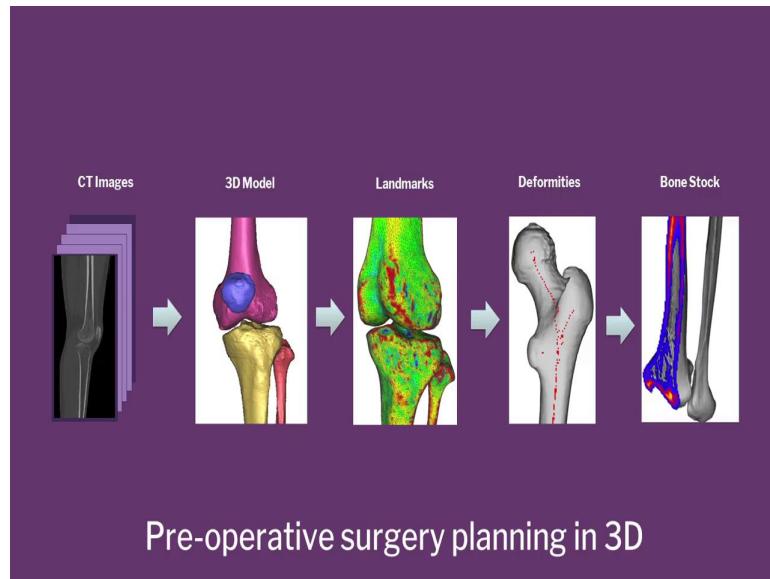
So the other way to do that is to create something which has a magnetic coil, or lets say something that responds to magnetic coil. If you put the leg in a magnetic coil, turn the coin on the coil rotates, magnetic field rotates, and then there is inside some nut or bolt will rotate. And then you can slowly lengthen it. If we lengthen too much then we can always do the reverse turning of the whole thing. But, these joints are very expensive. They are like 15 to 20 Lakh rupees, 25 lakh rupees. Ok.

Not only that even there is a limit to how much you can expand. It can take in about an inch or so. So, for at least maybe, instead of 3 surgeries you can now do 2 surgeries. But this is an issue which you cannot solve easily.

Design, Technology and Innovation
Prof. B. Ravi
Prof. B. K. Chakravarthy
IDC School of Design
Indian Institute Technology Bombay

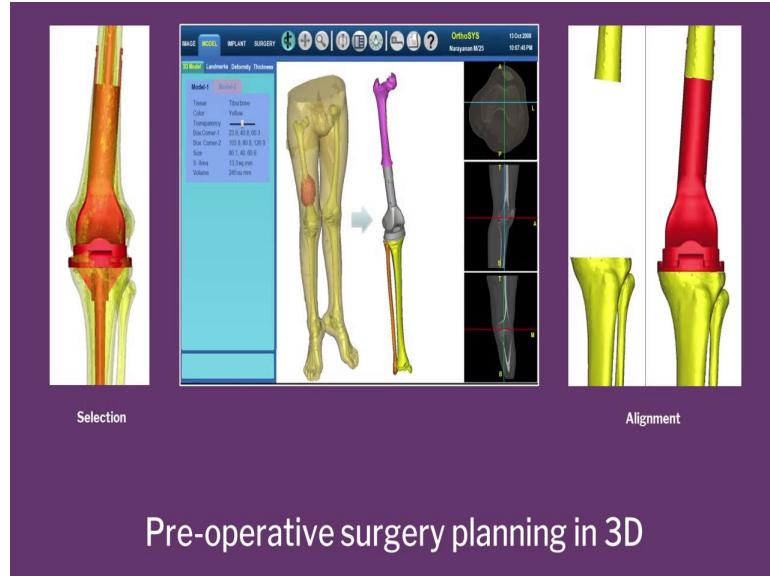
Lecture-11
A Collaborative Excellence Part 2

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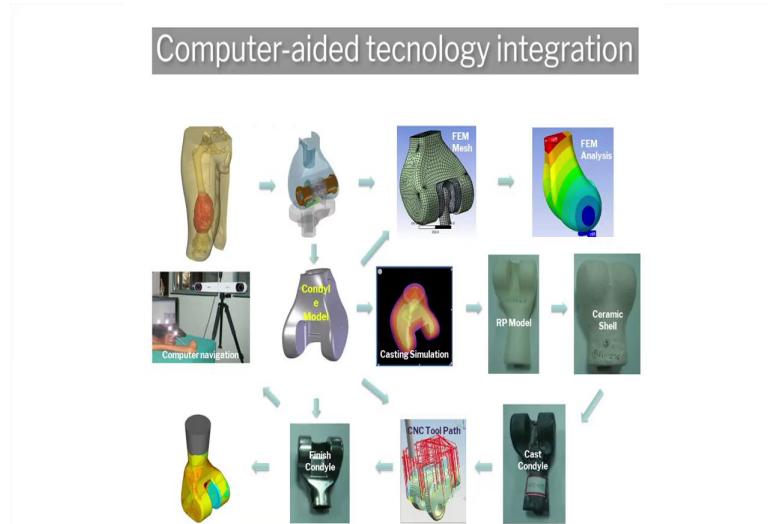
So, you do these instruments and then we also can develop softwares to plan the surgery in 3 dimensions. It is now possible to take a CT scan of the patient's leg, convert the CT scans into a 3d model, use a 3d model to plan the cuts, exactly where you will cut and so on. Transfer that information on to, maybe an application.

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Or take printouts, or make a 3d model of the joint or the cut part and all that and give it a surgeon so they will implement exactly what was planned on the computer. It further increases the probability of more accurate surgeries. So, finally what we did was to put together a host of technologies.

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We used CAD, we used simulation, both kinematic simulation, dynamic simulation, stress simulation. We used manufacturing simulation. At some point we used a casting process to make the joints but then we found the casting was not very reliable. We switched to machining process. There also machining path simulation. And eventually after all the things are done the inspection

using a 3d scanning and comparing 3d scanned object or component with the original CAD model. So we can use a lot of these technologies to make sure that you can get the things right.

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IIT research holds out hope for kids with bone cancer

Milika Basu

Solutions leading to affordable and long-lasting artificial joints, including accurate reconstructive surgeries for children with bone cancer, are being developed at IIT-B.

The project comprises of engineers, scientists and surgeons from IIT-B, Tata Memorial Hospital and Non Ferrous Materials Technology Development Centre (NFTDC, Hyderabad). It is sponsored by office of principal scientific advisor to the government of India. The group is gearing up for medical trials by 2006 end.

"Bone cancer primarily happens in children and usually affects the femur (thigh bone). Most of the tumours are observed just above the knee joint," said B Ravi, professor of mechanical engineering at IIT-B, who is heading the research group. "Now, amputations are not necessary as it is possible to cut out the tumour bone and replace it with mega implant. Imported implants are costly while the local ones a high failure rate," he said.

Called the 'orthoCAD' network research facility, the group is developing orthopaedic implants and surgery planning software for tumour knee reconstruction.

"The artificial joints are designed to give more freedom in movement and last longer. Innovations in manufacturing will reduce the cost to less than half," said Ravi.

A knee simulator machine is also being made on which the joint can be tested. A part of the project is a computer-aided surgery planning software. "The software reconstructs a 3D CAD model of the patient's anatomy from CT images. It will help select the correct size and position of the implant, thus improving the accuracy of the surgery," explained Ravi.

PROFESSOR B RAVI, Mechanical Engineering Department, DR MANISH AGARWAL, orthopaedic oncologist at the Tata Memorial Hospital and DR K BALASUBRAMANIAN, director of the Nonferrous Materials Technology Development Centre, Hyderabad

What
Orthopaedic implants; development of tumour knee prosthesis system.

What's cool
Children affected by a tumour in the knee will no longer have to undergo amputations, thanks to this affordable prosthesis implant.

Prof says
When doctors treat a bone tumour in the knee with chemotherapy, the bone gets weakened and the leg has to be amputated from above the knee. This technology replaces the cancerous bone with a bio-compatible metal joint that will be available for an affordable Rs 1 lakh. Such joints are currently available in the West but at a hefty price of Rs 4 lakh to Rs 15 lakh.

And of course we get newspaper coverage very nicely. This is just one of the many coverages which says that 'It holds out hope'. And you will see that a lot of papers do cover technologies developed in IIT is an IISc saying that some new innovation is there, it hopes to change the future on things like that. But then you very rarely see that it actually changed the life of someone. So we did not want to stop here. We want to go beyond and say that let us go beyond hope and let us show that it actually can change the life of people.

So, fortunately for us Dr. Chidambaram's office, who had funded the phase one of the project, they came back and said that, 'Why don't you guys actually go ahead and put the joint in the human body', patient's body and not just do a theoretical R and D project funding. And they released, in fact, a larger amount of grant, to do what is called as clinical studies or clinical trials. Clinical trial means you are actually going to put in human bodies. Now that sounds easier than done because there are lots of checks and balances before you actually go into human clinical trials.

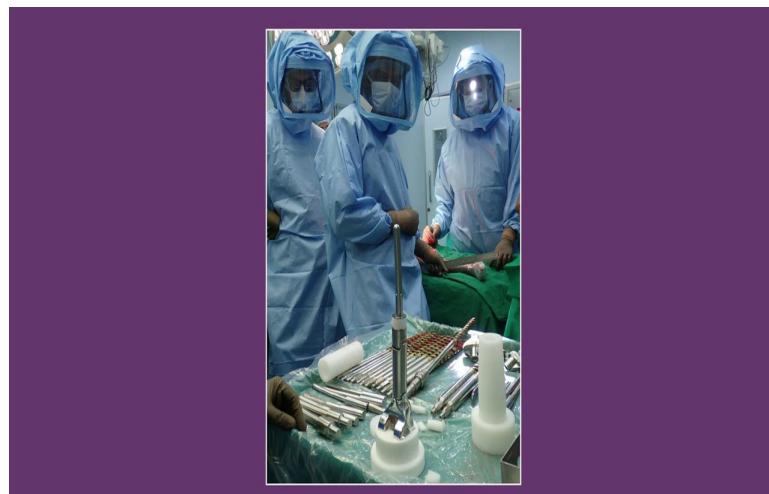
You need to do what is called a complete study protocol. How exactly are you going to do that? You have to put what is called as a policy inclusion and exclusion criteria. What kind of patients are you going to recruit? What kind of patients will you not recruit? Which hospitals will do that?

Which doctors will do that? What is the exact procedure for doing that? What will you do if something goes wrong? What about insurance for the patients? Training manuals?

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And then we actually manufactured the first lot, second lot, actual lots to put into the (patient).

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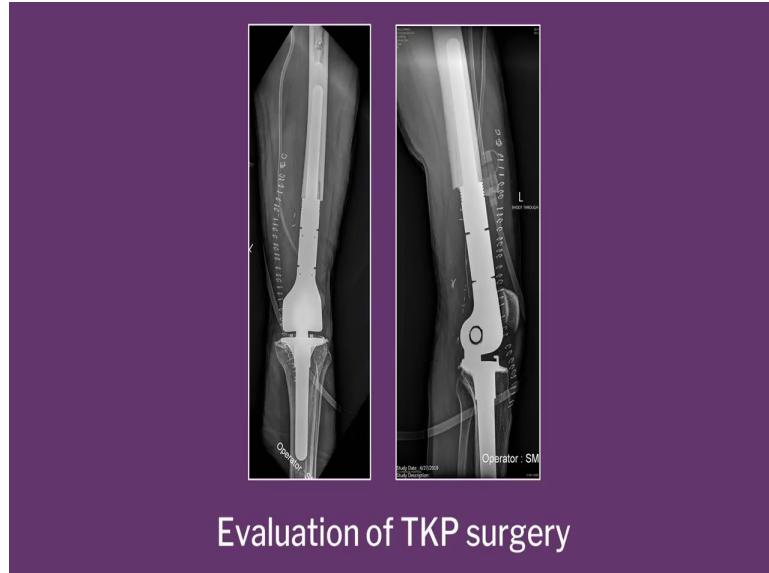


Preparing for TKP surgery

This is the actual photograph of the surgical team getting prepared in the hospital. By this time Dr. Manish Agarwal had shifted to Hinduja Hospital. And so we had to take permissions from the Government of India. It is called DCGI, Drugs Controller General of India and you also need to take permission from what is called as the Ethical Institutional Committees of the hospitals itself. And that is that actual (photo), 27 April early this year.

The first surgery using the Indian knee joint happened in the hospital. You see Dr. Manish Agarwal here. That is the team which you see in the photograph, is the team from the NFTDC, Hyderabad. They came down because they were so excited after so many years, all the manufacturing. Finally, it is going to be, going into someone's human body.

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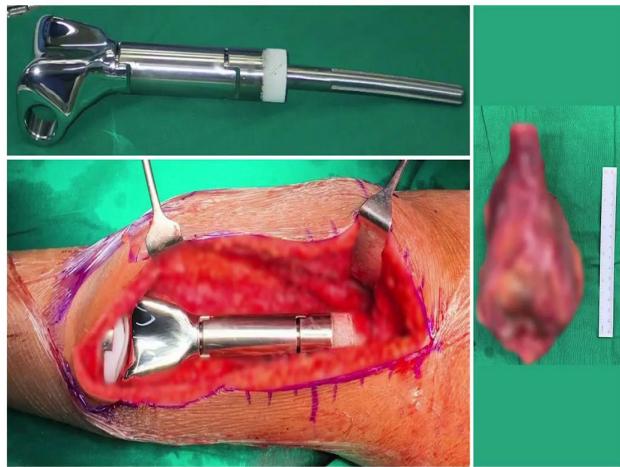
And then post-op surgery which you can see. The entire, there is no femur, there is no tibia, a part of the tibia. It's all replaced by the artificial prosthesis, right?

(Video Start Time: 03:51)

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Can you imagine, how many days after surgery? Second day after surgery. The patient is actually walking on his own feet without any crutches. Can you make out which leg? Because you saw L in the picture in the X-ray. Pretty natural right? Now the first surgeries happened and we were all thrilled.

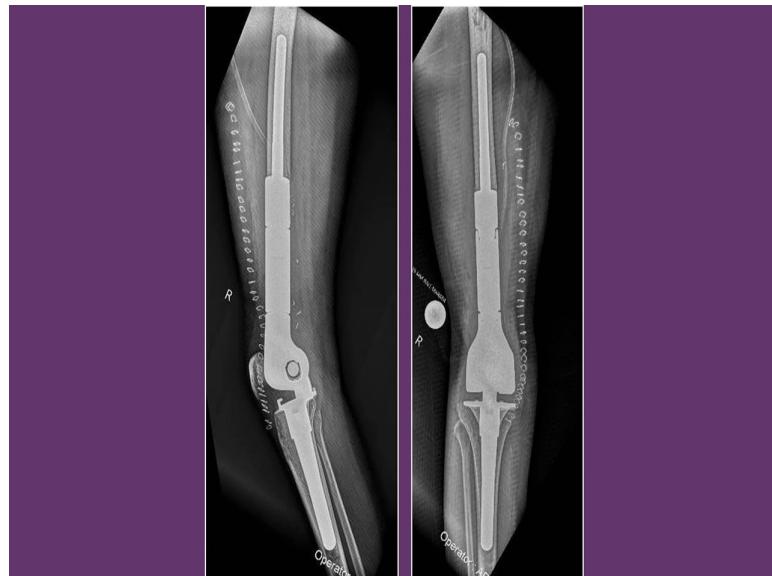
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TKP Surgery - 28 May 2019

And then a second surgery happened. Very quickly, within a month of that. Again you can see the entire knee, the entire prosthesis is assembled on the thing and the tumor, with the tumor again removed, and the entire gap is reconstructed with this knee joint.

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Again you can see very clean lines. You can see very beautifully they go into the bone. Perfectly centered right? From outside you cannot make any difference about the shape of the leg. And by the way, the natural, some of the muscles are retained. So the joint is inside, you preserve the muscles, you preserve the blood vessels and nerves. Nerves also, otherwise how am I going to operate the leg, and then you are going to put the whole thing back and seal the whole thing. These are nothing but your sutures.

Student: Sir, what is the relation with the kneecap?

Kneecap is still there. The kneecap glides onto the patella. The kneecap, this is the kneecap for you, it glides from the patella, just like a human, natural human knee joint. Some are lost because of tumors, because along with the tumors some of, some parts are taken off. So, I would not say this leg is 100% as strong as the other leg which is maybe good. But the loss may be as little as 10-15% of a good knee.

(Video Start Time: 05:24)

(Video End Time: 05:32)

So, this you can see the patient now, again after 2 or 3 days after surgery.

Student: Sir, what is the weight of the prosthesis?

Sir: Weight of the? About a kg. About 1 kg. It is a little heavier than the human body, maybe it is about, you can say, twice, almost twice you can say. But compared to the entire leg weight the incremental weight of the leg is not more than maybe 5-10%. Our leg is pretty heavy. They can almost sit squat on the, on the thing. If I remember, it is about 150 degrees. So, just to compare with the imported knee joint, ok, imported knee joint does not have this much flexion.



They say you will have to sit only on chairs. Mostly it is 90-100 degrees, imported knee joints. This can go up to 150 degrees, number 1. And we gave this beautiful, little bit of that movement because of which it won't, the stem will not take shear stress and break eventually. So this takes a

little bit of a, this is a little tight because it is not yet put on the machine. And these are the components which I can change. I can remove this component and put it directly on to that I get a shorter one.

But if a tumor is large, I can put a larger one of this middle part and I can build up the whole thing. And I can change this small, medium condyle can go with a small, it is called tibial tray and vice versa and so on. Mix and match I can do. So, I mentioned to you, this is cobalt chromium. This is titanium, this is also titanium now. This is also cobalt chromium. Now we are making it out of titanium. This and this is your Ultra High Molecular Weight Polyethylene.

So you don't put metal to metal movement. Movement should never be metal to metal. It is moving on a polymer. And there is an axial here, and that is actually where our design innovation came. We are patenting that. And even the axial is surrounded by a poly bush. So again there is no touching or contact between metal to metal. And if there is no other adverse, usually they go by adverse patient's reporting. Patient says I have, pain has increased or something is happening.

For example the imported joints, there was no shaped 'poly' like that. This whole thing can rotate freely. So, patients are very uncomfortable standing on their feet. They would say, 'No, no I want catches, someone should hold me', and all that. Because this naturally stops nicely, you saw the patients walking, this patient walked with a walker. The previous patient could walk without a crutch also.

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And that is the 3 culprits. Yeah it happened because we 3 hung on, for the whole, whatever 15 years. Without these people I would not have gone for the, in fact Dr. Bala on the left side, he is one who is taking the actual punishment. Actually taking the lead, manufacturing that and so on. So, I only started that. We did not give up. India, sometimes it is very easy to give up because there are always obstructions. I have not told you about all the obstruction we had in the project.

It will take you two hours to talk about all of them. Lot of frustration and a lot of obstructions, a lot of times, but we never thought of giving it up. We always say, ‘no let us keep pushing, keep pushing, keep pushing’. Even now 100 patients are going to be, you know, operated. Only two are over, across 5 hospitals, across the country. They had 10 orthopedic surgeons who are going to come in and they have been trained to do this.

And like, you know, and basically then, there will be the next stage. That will be the pilot, right? 100 will be a pilot and then the next stage of large-scale implementations. Now, Prof. Ravi didn't mention about a very good thing which happened in all this is, both the manufacturing, the NFTDC, and Prof. Ravi's lab, that is called the BETiC lab, now, much more, you know, large-scale innovations are happening and Prof. Ravi will come back again and talk about all the other large-scale innovations.

How he is building entrepreneurs, how he is building, you know, biomedical innovations and how he, you know, conducts the hackathons, you know, all that, you know, will come again in the next session.

Student: Sir, so we cannot insert the screw from outside because there are chances of infection, and we cannot open up the (leg), to place another module inside because that is also a very big process. So, can we calculate the average knee movement per year for children and insert a lever in the knee movement so as per the knee movement per year the prosthesis starts expanding.

Sir: Good idea, good idea. I know what you are saying. It is a good idea.

Student: and now we have since you have shown me the manufacturing in dye molding machines in the beginning, now we have MOD machines that can go up to the accuracy of 5 cm, sorry mm, which we saw in the last few classes.

Student: It can be paired with an application like Google Fit and all which can tell how many steps are remaining to increase by how much, which children can get used to grow.

Sir: Or you can tell them quota. The quota for this year is, you know, 5 lakh steps.

Student: Sir, because children hit puberty at different points so that also matters.

Sir: I can always go a little more a little less depending on how much you are going. I think it is a good idea and sometimes growth happens in, in sports. Growth is not always uniform. I have not heard about anyone thinking about something like that.

I told you the two mechanisms which already exist in the market. Definitely worth thinking about. So, chase it and I am there with you right behind you. Do it, yeah.

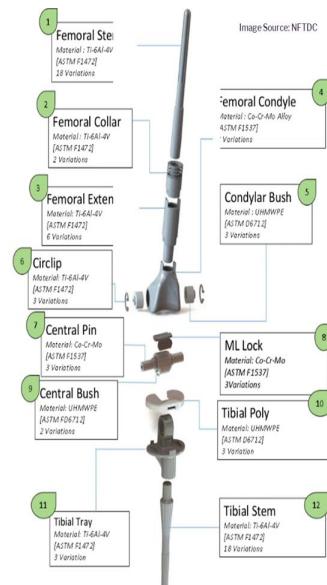
So, further to Prof. B Ravi's presentation, let me show some, very, you know, interesting interventions from design. And all of you are, you know, design students and you have Applied

Ergonomics (a course provided to B.Des students at IDC) right now. So, let me show you some parts of that from a real case study.

So here like, you know, for example, what would a designer do in all this? So, I was of course part of the team, you know, always supporting and being there in the meetings and during the building of the prototypes and for the suggestions and critics, but a very important aspect is, if you look at the total number of components, how would the doctor who is operating understand all the components? How would each component fit each other? what type of fixtures and what type of you know aids will I give him to understand how these things go into one another? Right?

Because it is going to a new doctor, right? An orthopedic surgeon will just get this prosthesis and he has to operate upon it. He may have to do some training, he may do some, you know, manual.

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Can you see all the parts? The femoral stem. The femoral collar. Different stems at different heights, because the cancer is at different levels. So you have different heights. So, here you need a stem to attach this to this, femoral stem. And this is a femoral extension, to attach this to this we need an extension. And this extension is also of different sizes depending upon what the, you know, conditions are. And then, you know, the most interesting part is the circlip after assembling the, you know, circlips which you have seen moving parts with a round spring like, you know, grips.

So these are the serve clips which get attached and these are two bushes which go in. Ultra High Molecular Weight Polyethylene. This is the very, very high end engineering polymer which is specially designed to, because it is very human friendly point of view. And this particular thing is again made of that because it is a rotating part. And then you have the central pin which is sitting in between. Remember the, you know, it could move. So this central pin is oblong and this is the lock to prevent it from moving, the ML lock that has been inserted first. This is the Tibial Poly it is the polymer between the two joints.

Then we have the, you know, like aspects of the Tibial tray in which this Poly sits and the Tibial stem. So, now I want to tell you about the, you know, next phase. What happens with so many parts. Is it too complex for the doctor? Is it very easy for the doctor? Is it too complex for the operation theater?

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Positioning of the Supporting staff during the surgery

This is a mega operation so what happens, you have tremendous amounts of preparation. So, the whole team prepares with the, you know, in line. As soon as the doctor says you are to give that type of thing, and all of them are autoclipped and, you know, sterilized. Different types of, you know, like instruments. Some instruments are common operating instruments and some of them are instruments for fitting your prosthesis and those are called armamentarium. Armamentarium is the name given to the tools which are used to fix the prosthesis.

And that is given by whom? The armamentarium is sent by whom? The manufacturer of the prosthesis. So, he will send you the kit along with the tools. The prosthesis along with the tools. So, this is the operation table happening and these are what are the trays with all our armamentarium. These are called dummies. Very interesting. Within the armamentarium you have dummy pieces to check. So, there are dummies to put and check and then you are opening the sterilized prosthesis component. This is a collar to open it sterilized and then use this because it is very expensive. So dummies can go to sterilization are key.

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Positioning of the Supporting staff during the surgery

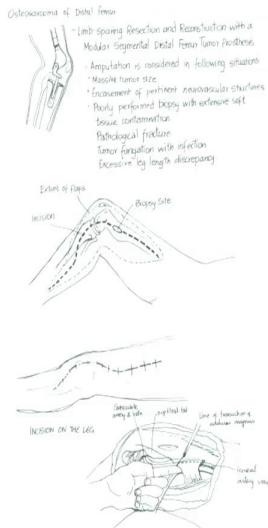
So, look at the, those are reemers' and all the tools which you see over here. The drills, and you cannot drill the bone at one go, right? You need to drill it slowly and you need to drill it at the right dimension because your stem should go in and lock, though you use something called the bone cement. The stem goes in, it's like, you know, carpentry and cementing. There is no difference. But here, most of the materials used for all these purposes are very advanced.

So there is a bone cement and you reeme accurately, put the bone cement and put your stem, the stem integrates of the bone. This is all, you know, the study I am showing you, is done by an M.Des student of mine who joined me in the studio. Worked with me for one year to support this whole prosthesis development and taking it to the pilot production. You are going to 100 numbers right. We had to train 5 doctors, across 5 hospitals to get this work done. How will I tell them how to do the operation?

Whereas Dr. *Manish Agarwal* who was the doctor with us for the last 14 years, he knows it very well like the back of his hand. You just give him the prosthesis, he will quickly, you know, assemble and put it. But for a new orthopedic surgeon, you need to tell everything about all their aspects.

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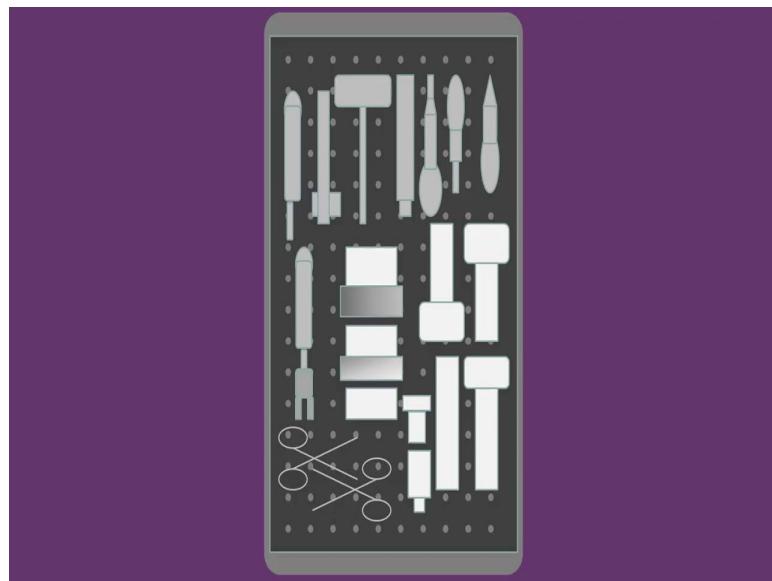
Developing clear insights into the operation procedures



And how will you do that, so these painstakingly, you know, *Dattaram Chari*, our project associate, would sketch every component and every aspect and create a manual for the doctor. He talked about every part of the tool being used. How is the tool being used? How the armamentarium is being used? How will you put it? How will you mallet? How will you cement? What will be done when? Created the complete journey for the doctors till the stitching back.

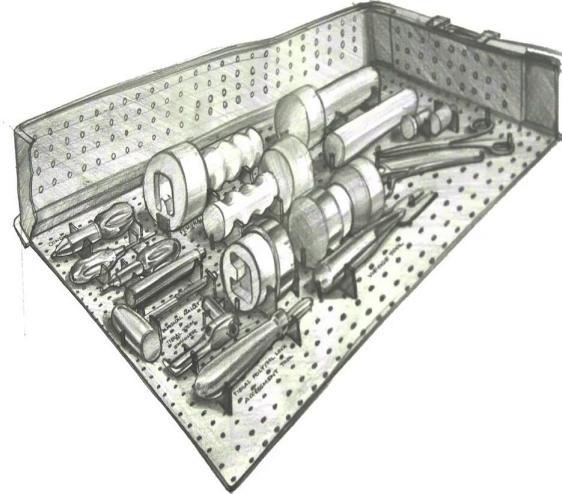
So, this is how the whole process goes in and this is the step-by-step process. So, now we need to also design the box for our product, right? Because we are designing a new prosthesis.

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So, we have to design the armamentarium box and the packaging for our product.

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So, we studied what type of sizes we are getting. What type of components we are getting. These are the initial ideation sketches.

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Surgeon's Insights

- Unless and until the basic things of the products like usability, packaging and handling are clearly defined & finalized, the product can't be granted a medical approval.

Then the surgeon's insights were taken. Very clear, surgeons were very clear that, you know, like, unless and until the basic things of the products like usability, packaging and handling are clearly defined and finalized, the product can't be granted medical approval. It cannot be granted medical approval unless you have all these things clear. You are looking at a world prosthesis. So, how can it be implemented? What happens? Whatever packaging we use? Becomes very, very critical in the whole journey.

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Surgeon's Insights

- Doctors and surgeons will actually use the instruments in a non - case for understanding the basic look and feel and understand the handling of the instruments.

And doctors and surgeons will actually use the instruments in non-case for understanding the basic look and feel and understanding the handling of these instruments. So, for this you know what we did? We bought a mannequin, cut the leg, made holes in the mannequin and we got the doctors to operate on that mannequin and all that idea was from our designer *Dattaram Chari*. The doctors were amused and they were very happy because they never did that before and they found it very easy to learn.

And this whole workshop was done in NFTDC, when they were all visiting them and they all checked how things are happening because here you can, you know, play with the leg, you can cut the leg, you can, you know, put all the things inside. And it was very open and it looked, that is the beauty of design see. We do the things which are the trials, the theoretical aspects, doing a mock-up study. And that we fed in and then everybody was extremely happy that they could ponder a lot of issues of, you know, some pin not being, how will you adjust the clip from the back, it was very difficult.

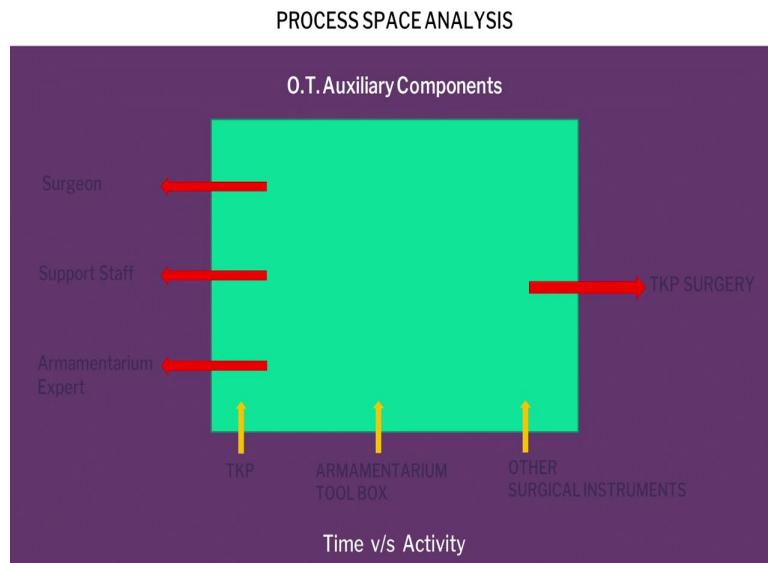
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Preparation for the surgery

Armamentarium and Process Understanding

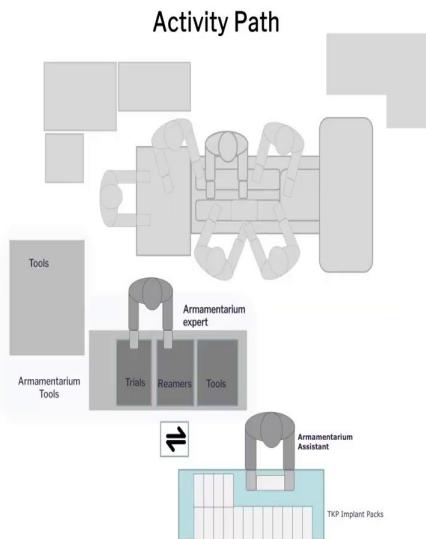
So, if now looking at the preparation for the surgery.

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So, when you have a theater, operation theater, it is a very complex phenomenon of people around you. There are anesthetists there are, you know, multiple helps with the doctors. They have their senior doctors, there are junior doctors, there is the main operation surgery and, you know, and there are these people whom the prostheses manufacturer sends. Because they are, they know their prosthesis well. So those people are also inside the operation theatre. This was the first time we got to know that even the manufacturer sends his person there to stand there to get the things done.

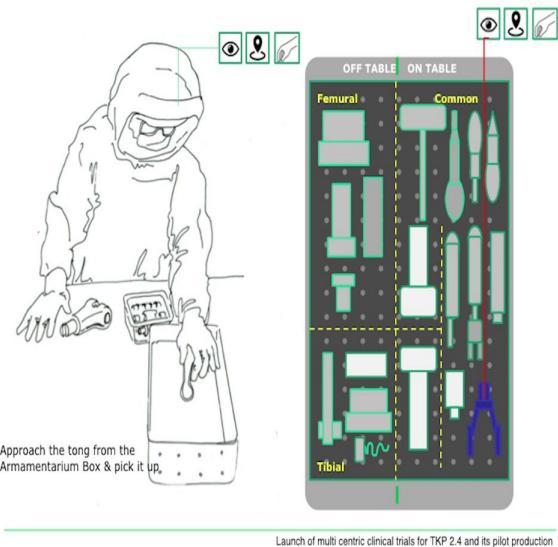
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So, we were just, you know, we made all these components you see. Where all you will keep what? The tools, the reemers, that trials, the dummy trials, and then here we have the armamentarium tools. And those are how the doctors will be all around the patient to get the operation done. And there is this armamentarium assistance. So, these experts and his assistant come from the manufacturer. So, what type of study did we do? We said, ‘we had to make this box very user-friendly, right? That is our job. As a designer I want to make everything easy for the doctor. So, very clearly, we had divisioned about off table and on table tools.

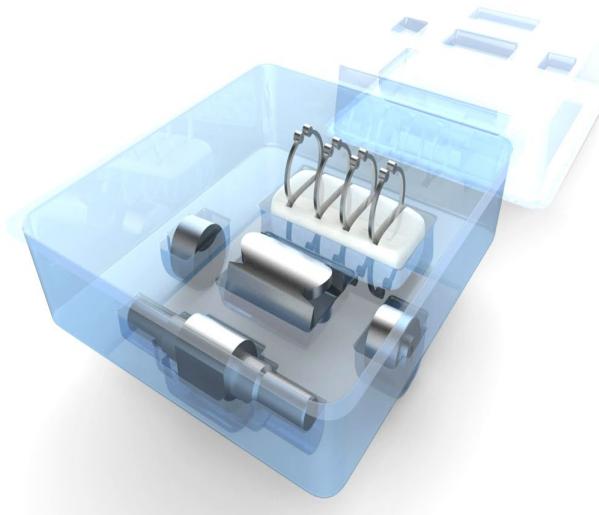
What is this off table? You have to assemble some of the components there and give to the surgeon and he would put that, put it inside the, you know, bone and then, you know, he will have some tools to put the circlip, to put the clips inside, to put the sockets inside, all that will happen with them. So that is the ‘On table’ and that is the ‘Off table’.

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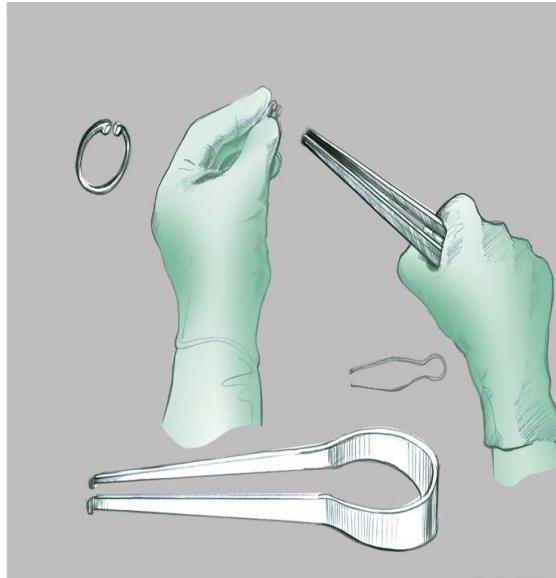
So, he made a division so that it is easy for the doctors and therefore the assistants to pick up. See how nicely it has been done.

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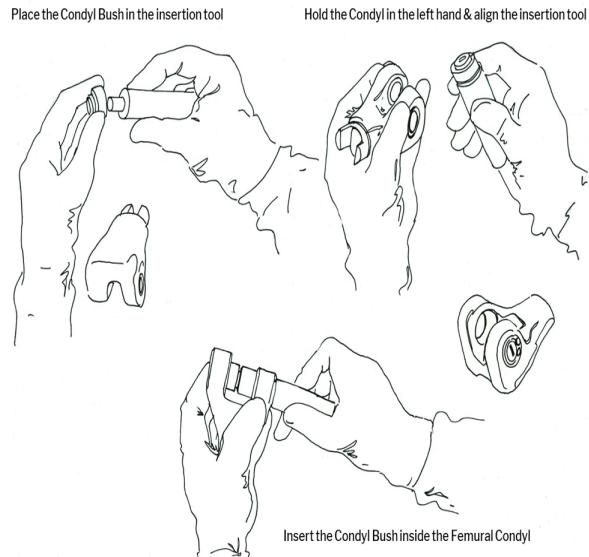
And then he packaged the product so it is easy to pick up. Look at the packaging. These are the clips which go and lock the pin which is being used and there are two extra clips if a clip falls down. It has a special tool to hold this, like this, open it, push it in and leave it. So, because it is spring-loaded what happens is every chance that it may go away. So, there is extra 2 given which are completely sterilized which are available for the doctor.

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And designing of the clip holder and how it will work also is part of the armamentarium design. And we created the grips, and what type of openness we need to have, what type of profiles we need to get and all these things were done. And every part the 'On table' and the 'Off table' as its each tool was considered taken.

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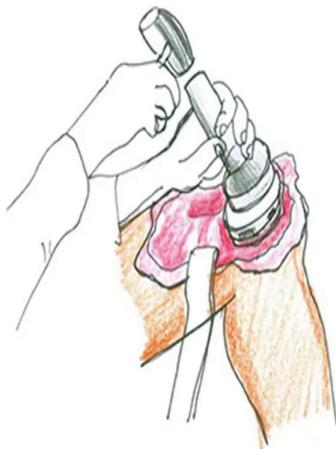


And a process was defined of what will happen. Remember there was a picture board to show the process of operation. Now there is a picture board to show how each part is being worked upon and that made it very, very easy and useful.

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And then again the surgical hammer. What type of load comes? How heavy should we make the surgical hammer? Because you were tapping it once it can damage the whole body bone, for example, so you need to really have a very, very right type of weight for the right type of application because you are sending the stems inside by actually hammering.

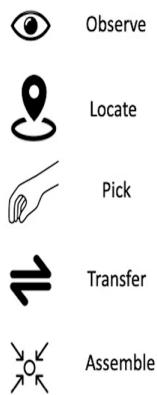
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Inserting the Tibial stem

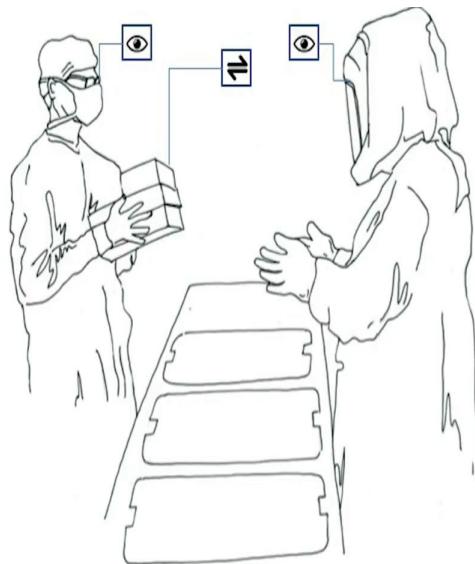
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The User Product Interaction



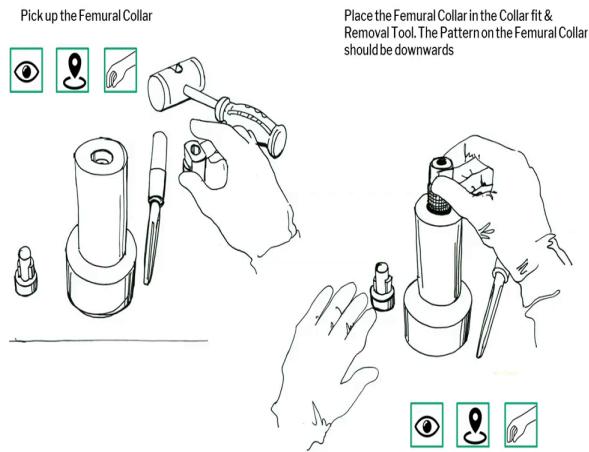
He made this, you know, aspects of viewing, locating and holding.

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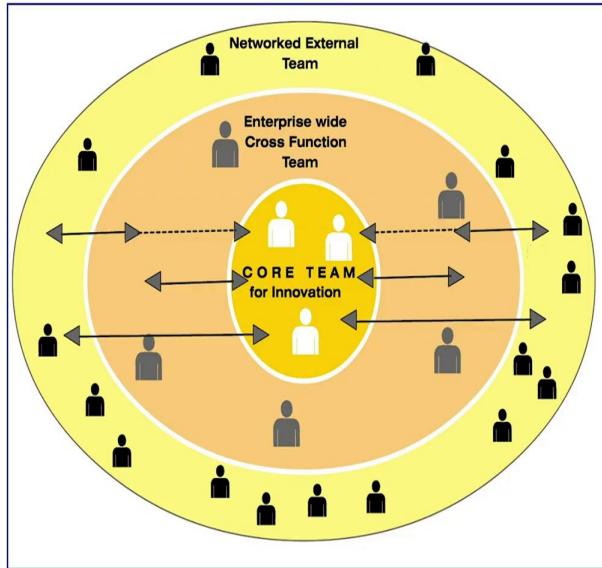
You have to see and you to pick up. For example the sizes, you do not have to catch it, you know, you just have to see the size because there is a large text over there, small, large, so you can pick up. So, this particular thing is a locator, you have to take them and pull them in the location and then this is about actually handling it.

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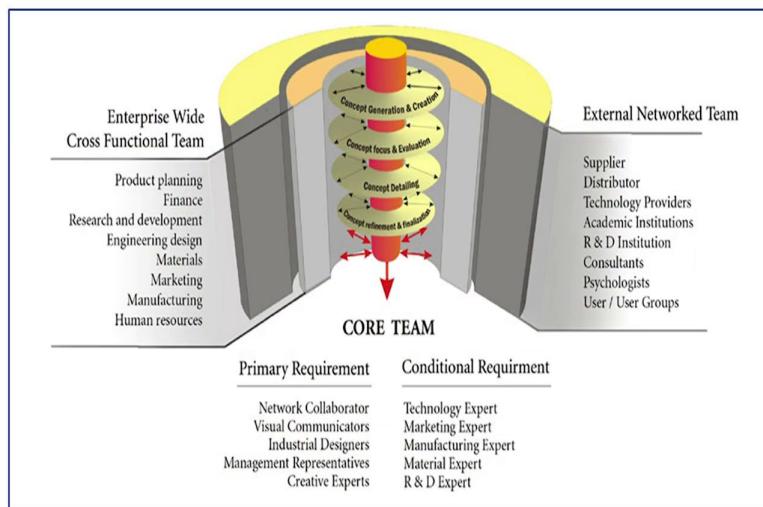
So, these are the three icons he developed to make it very clear that, which of them you are not touching, which of them you are placing the right location, which of them you are opening. See it is a very big risk if you open 3 sizes unnecessarily. You have lost the sterilization aspect. Your repacking aspect is very, very expensive. So, we talked about the tibial side, the femoral side, see, very clear because they are two sides of the table.

The bottom side and the top side and then the common tools which are going to be used and every component was considered and what type of activity will happen was, you know, taken care of. And that is how the whole, you know, operation planning was done. So, that is the whole journey of the designer intervention of how I, as a part of the support team,



so, there is a core team. There is a support team like me. There were a lot of people in the support team.

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And then there was this larger enterprise-wide team. So, the teaming was very interesting here. The first team consisted of the 3 professors who work day and night and their team members, there are at least 4 to 5 team members. Prof. B. Ravi had at least 10 to 12 M.Tech students and 4 PhD students whose contribution was there in this. Research contribution. So, we have a whole large team of support structures also behind all this and taking things forward.

So, this closes our, you know, like, understanding of how, you know, how we need to really work across domains, across disciplines and without each other's strength and input this product would have never come up. And the biggest, you know, credit is also to the principal scientific advisors office which is the Government level, its the Prime Minister's, you know, they would directly report to the Prime Minister.

The principal scientific advisors office and their office was in constant support all these years. With the type of funding which came in was very, very large. Without this type of funding this activity could not have happened. So, with that aspect now we got everything for the first time. There is no prosthesis in the country. So, first time the DCGI, you know, the Controller gave approval for this. That was the first time, because to doing first time they took 8 or 7 meetings to get this cleared.