Design, Technology and Innovation

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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.

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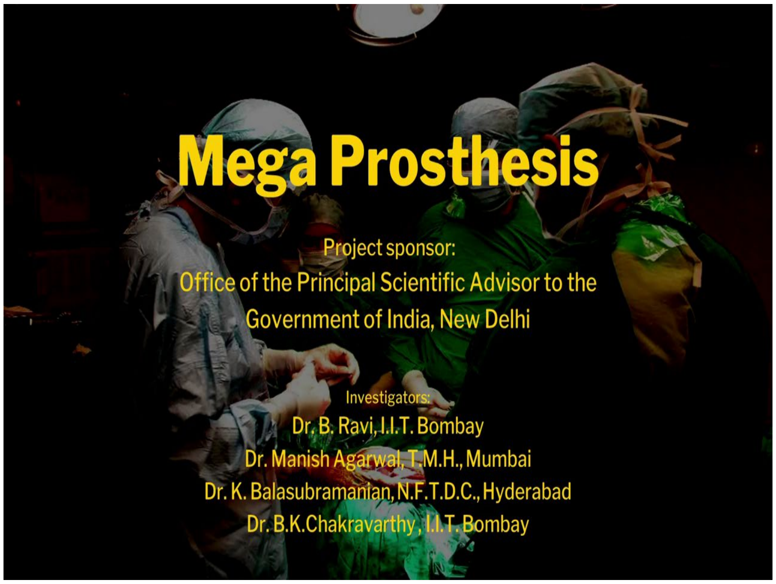

This Mega Prosthesis is a knee implant for children who are suffering from cancer in the knee and here, for example, if you do not have this mega prosthesis, the doctors would have to amputate the leg. This is a very, very interesting, sort of project, I am very fortunate that I was not the core team, 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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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.

Student 3: The movement of the prosthetic leg, and he also goes through impacts, jumps and walking, everything, how does it (the prosthetic knee) deal with 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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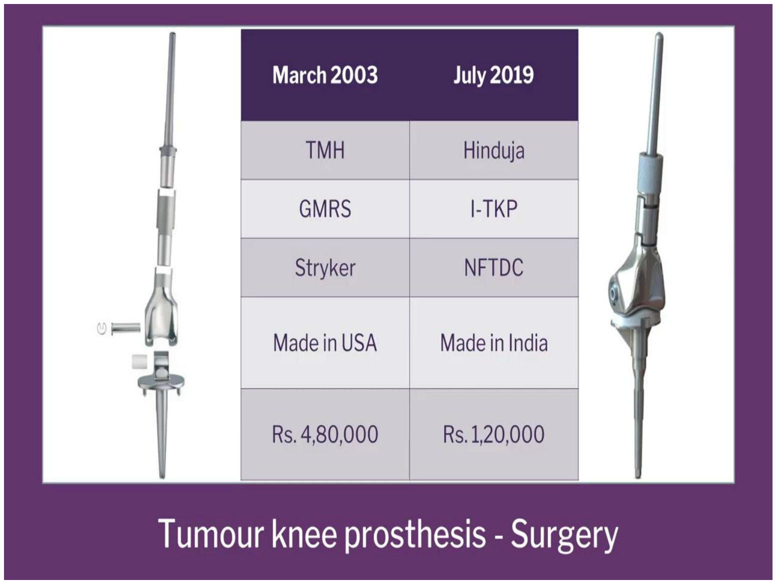

There are 2 implants which you can see in the picture. There is a big difference between the two. The first one, is an imported implant. And, it is about 4.8 Lakhs rupees as you can see. The second is what, the one which was developed in this project. One fourth the cost. But between them is a long story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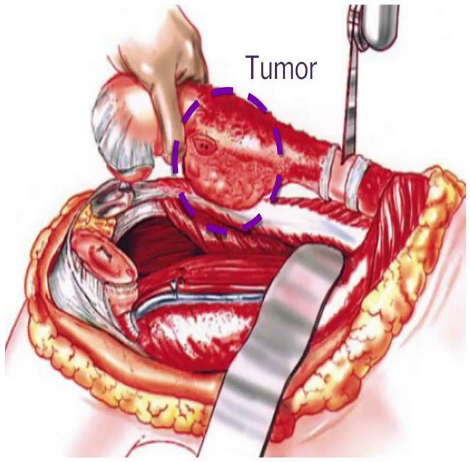

Removal of knee joint with Tumor (with bone)

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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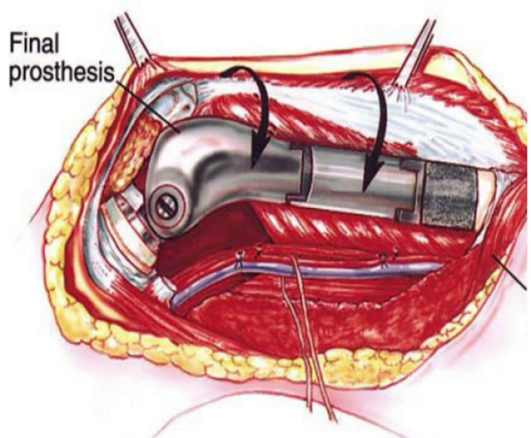

Mega Prosthesis Knee joint

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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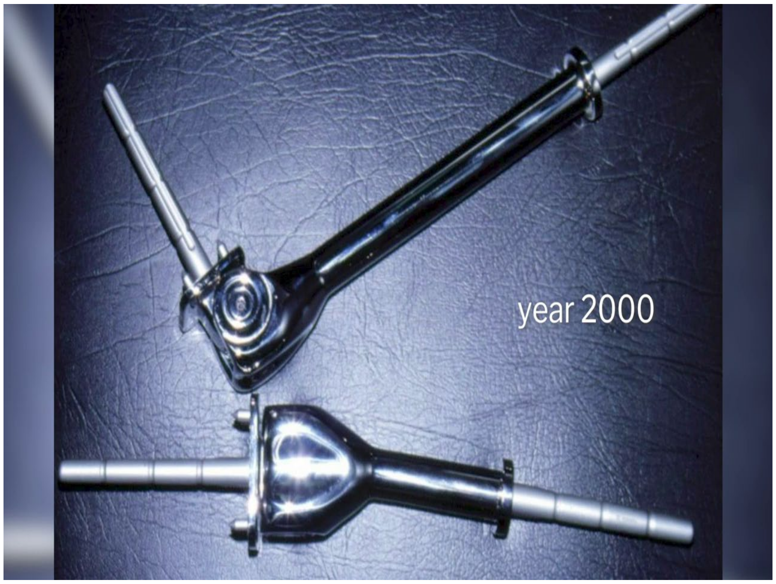

He started benefiting a lot of patients who are otherwise very poor to afford the imported knee joints.

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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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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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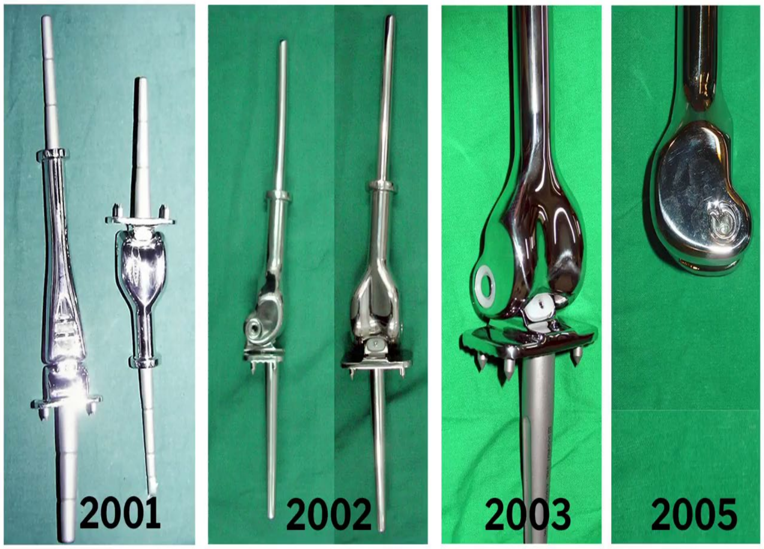

And slowly started improving the joint parts. So the patients were benefiting, joints were improving but only after sometime, you started getting some problems.

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Surviving cancer

A SRINIVAS

In Std IV, Nikhil Mane told his Sanskrit teacher Madhuri Chandak that he would make it to the SSC merit list.

It's been a dream that he has clutched on to for six years—even through the toughest period of his life after he was diagnosed with bone cancer in Std VIII.

The Chandrakant Patkar English Medium Vidyalaya, Dombivili, student spent the next nine months in Tata Memorial Hospital, where he underwent chemotherapy and studied and passed his Std IX.

On Thursday, all his efforts bore fruit. Mane, who still has a limp from his knee replacement surgery, scored an inspiring 91.73 per cent to top the handicapped category.

"I want to be an oncologist," he said, adding that Dr Manish Agarwal, an orthopaedic oncologist at Tata Memorial who performed his knee replacement surgery, was his role model.

Dr Agarwal shrugged off the compliment. "It's easy to have role models at this stage. All the credit goes to Nikhil for going through chemotherapy, nausea and hair loss, surviving it and topping his exams."

Father Chandrakant, a chemist with Reliance, and mother Shobha, a homemaker, could only say their son ...

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.

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Boy battles cancer, topscores with 92%

Times News Network

Mumbai: The stairs to his classroom were rather steep but Nikhil Mane preferred to climb them on his own. The physically challenged SSC topper has never let his bone-marrow cancer dent his determination. And not surprisingly, the boy who scored 91.73% wants to become an oncologist.

Despite nine debilitating sessions of chemotherapy and leg surgery, Nikhil continued to hit his books, driven by the desire to excel. "He became a more determined boy after he fell sick. He has strong opinions on everything and nothing stop him," says his mother Shobha.

Nikhil's success is a measure of the strength of the Mane family that has weathered several storms. Father Chandrakant was an employee with Nocil until he was laid off when the company's Navi Mumbai plant shut down two years ago. It was only recently that he found a job with Reliance. "Financial troubles were there, but some trusts helped us," he says quietly.

Today, his pudgy, bespectacled son has done the family proud. The Manes and Nikhil's Sanskrit tuition teacher Maduri Chandak, who accompanied them to school, can't stop beaming.

Nikhil Mane

▶ He eyed general merit list

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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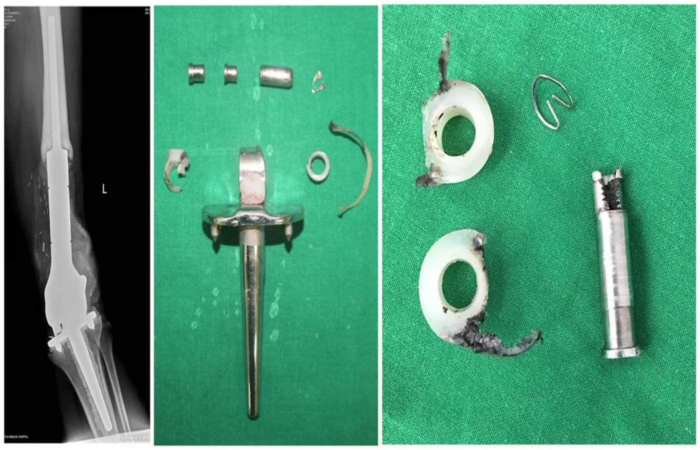

Early Failures - Metallosis

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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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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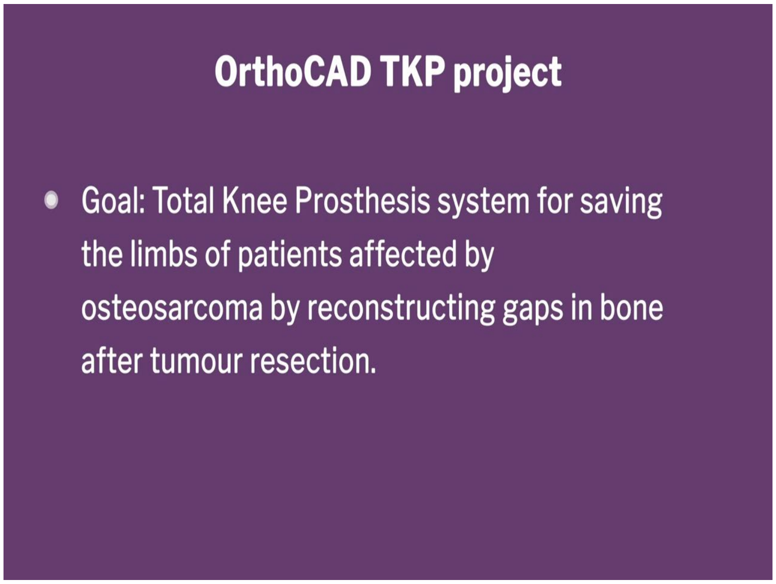

And we said we will develop this Tumor knee prosthesis for children affected by bone cancer.

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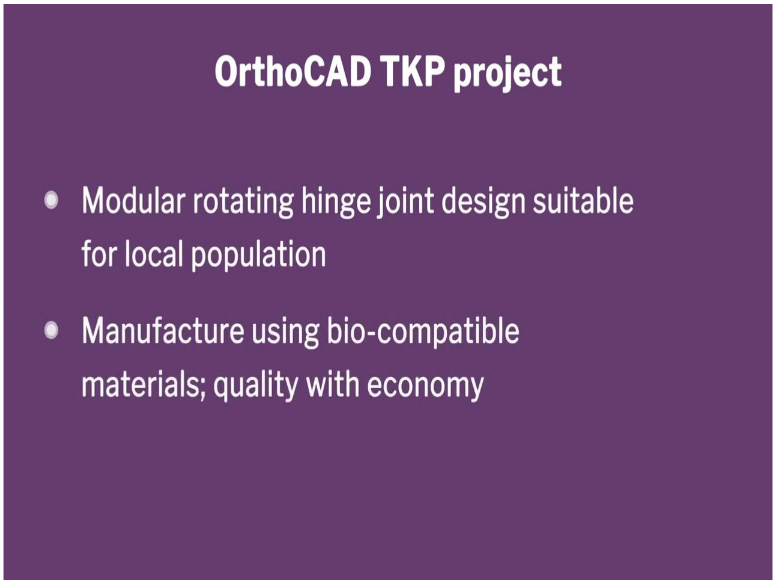

And we also said, we will create a novel kind of hinge design, we will use biocompatible materials. We said we will test the joints before putting in patients. Ok?

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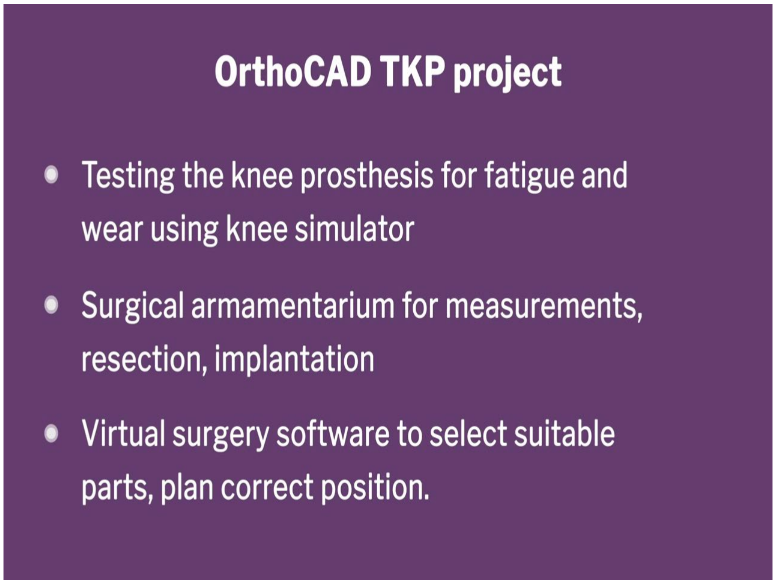

We also said, we will create instruments to do the surgery properly and we will also try to do a software development to plan the surgery in advance. In other words, not just one product but also the entire system of things which you need to make sure that product actually goes into the patient successfully. 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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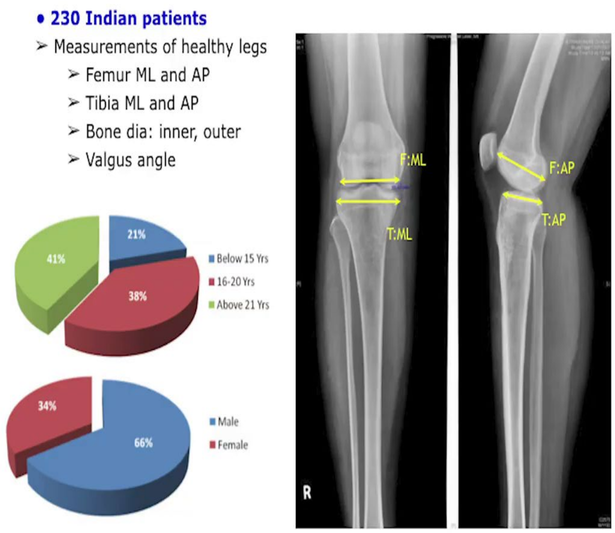

So we went ahead to measure the dimensions on X-rays of hundreds of Indian patients to get to know what are our sizes, our standard sizes and then we clustered it to create a small, medium large size. Otherwise American small size is equal to our medium size. But again then the shape is not correct. 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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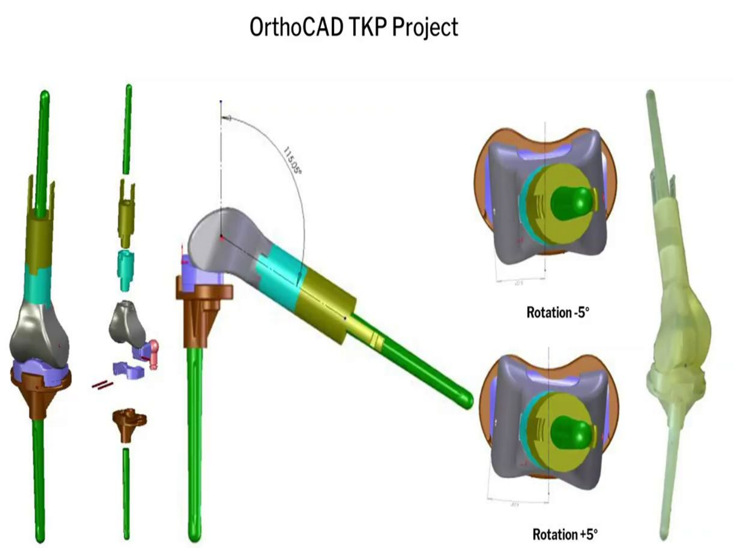

So we put an extra rotation in the whole system. Also we did not want to copy the imported joints. So we had created our own methods of creating, giving those moments. So, it can be patented, otherwise it cannot be patented. You cannot copy something which is already patented by other countries.

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

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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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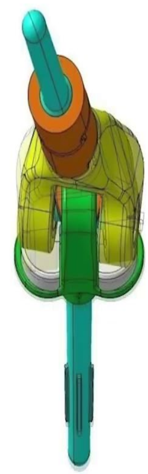

Maybe this size is not correct, do like that, this moment is too much or too little'. So, every time they give a suggestion, you go back to the drawing board, modify that, create another model and go back to him. Do you have any clue how many times we made the modifications and built the models? It was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

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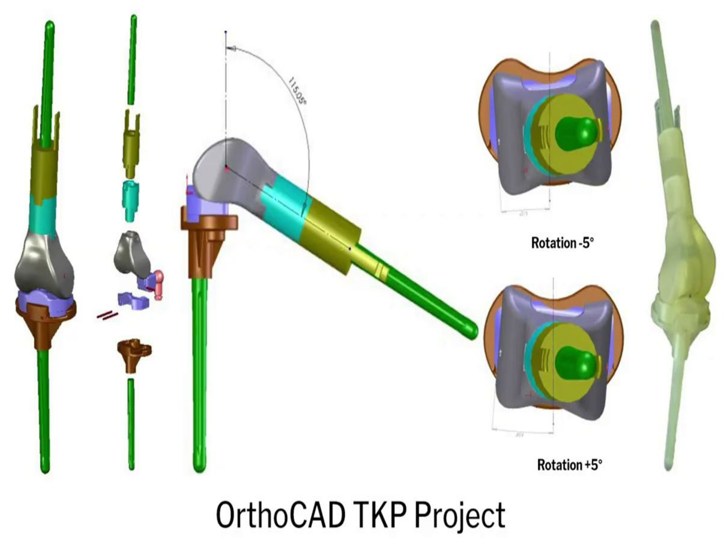

And the doctors, what is there, they say that, 'This slightly more curved it should be', but the thing takes hours to change, model on CAD and then may be days to manufacture on a CNC machine.

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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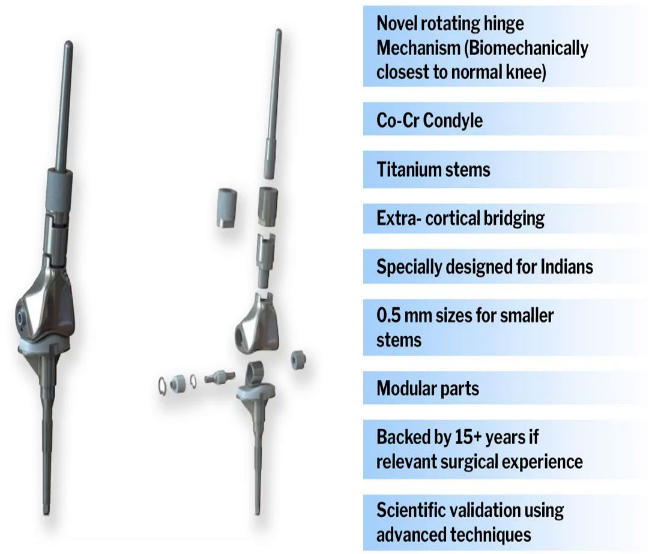

So we took a middle path. We said we will make what is called as a modular joint. A joint which has a small, medium, large size of as you say the Condyle. The middle large part will have different diameters of the axis or the stems, which goes into the bone at the end, and it's all mix and match. You 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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And they put new equipment for manufacturing this design.

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So, we had CNC machines.

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We had robotic polishing machines,

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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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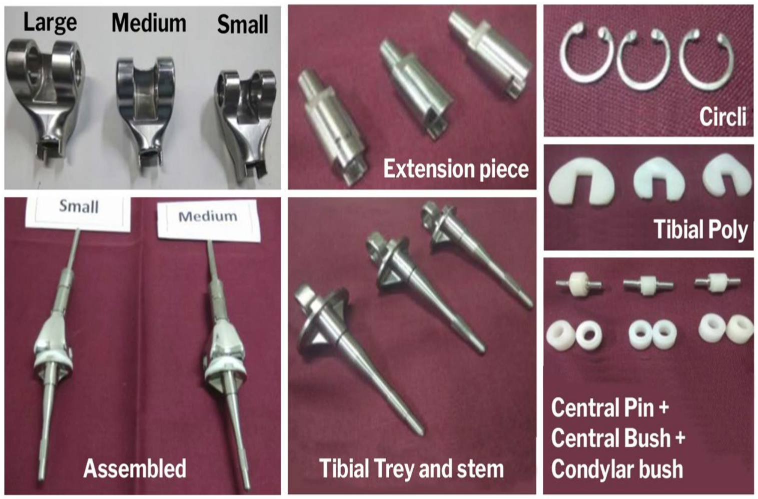

TKP 2.4 Parts manufactured at NFTDC, Hydrabad

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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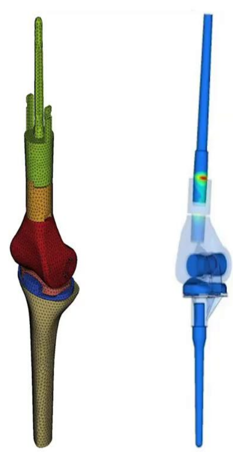
Virtual and experimental testing at IIT bombay

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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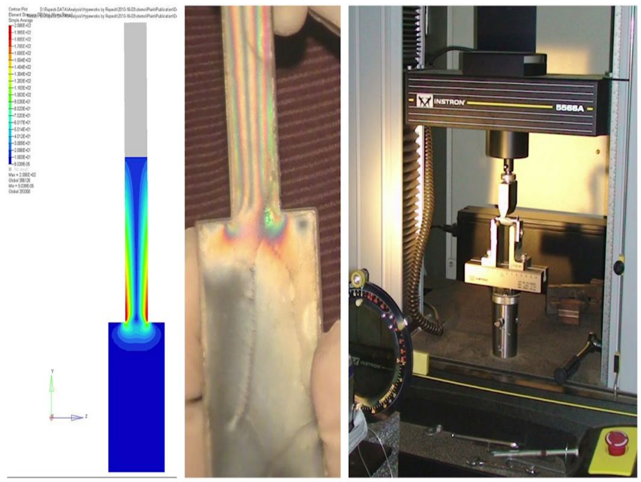

Physical stress testing

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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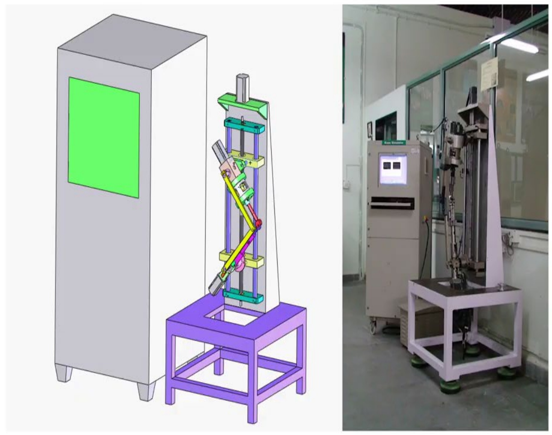

Fatigue & Wear Testing on Walking Machine

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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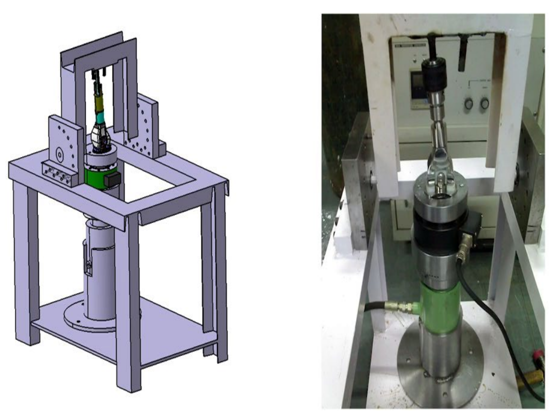

Second generation machines developed by NFTDC

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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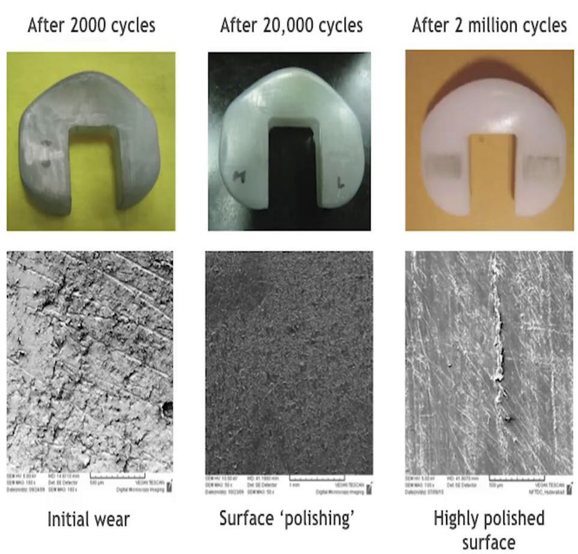

So,this one which we showed the picture here, it's a polymer part. I did not mention to you the material of the joint. So, let me tell you that now. So, stainless steel is bio-inert. It is neither friendly nor is it an enemy. But if you want to buy a bio-friendly material, it is titanium. Titanium, if 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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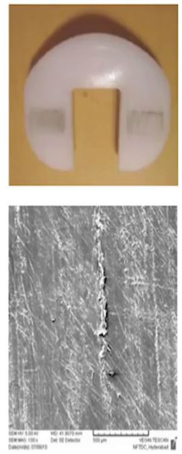
After 2 million cycles



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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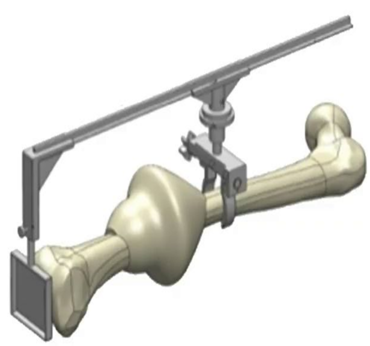

Initial design of surgical instruments

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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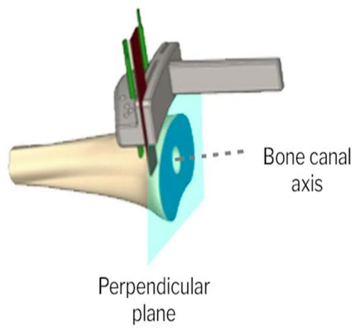

Initial design of surgical instruments

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.