Design, Technology and Innovation
Prof. B. Ravi
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Indian Institute Technology Bombay

Lecture-11
A Collaborative Excellence Part 2

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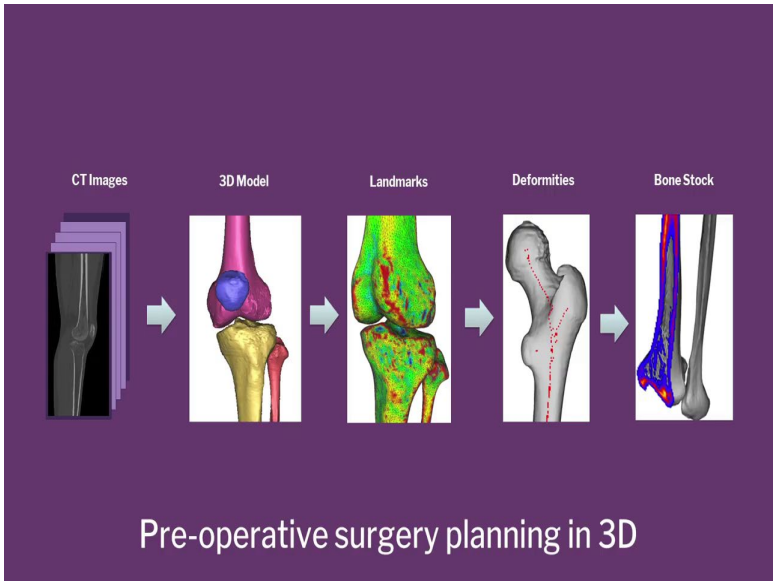

So, you do these instruments and then we also can develop softwares to plan the surgery in 3 dimensions. It is now possible to take a CT scan of the patient's leg, convert the CT scans into a 3d model, use a 3d model to plan the cuts, exactly where you will cut and so on. Transfer that information on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

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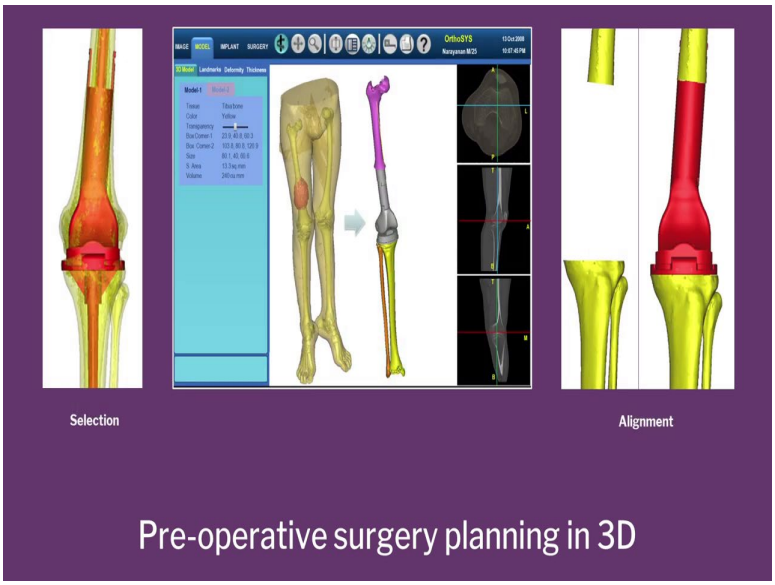

Or take printouts, or make a 3d model of the joint or the cut part and all that and give it a surgeon so they will implement exactly what was planned on the computer. It further increases the probability of more accurate surgeries. So, finally what we did was to put together a host of technologies.

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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

Mihika 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 2009 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 3-D 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.

A knee simulator machine (left) on which the artificial joint can be tested. (Right) A model of the tumour knee prosthesis

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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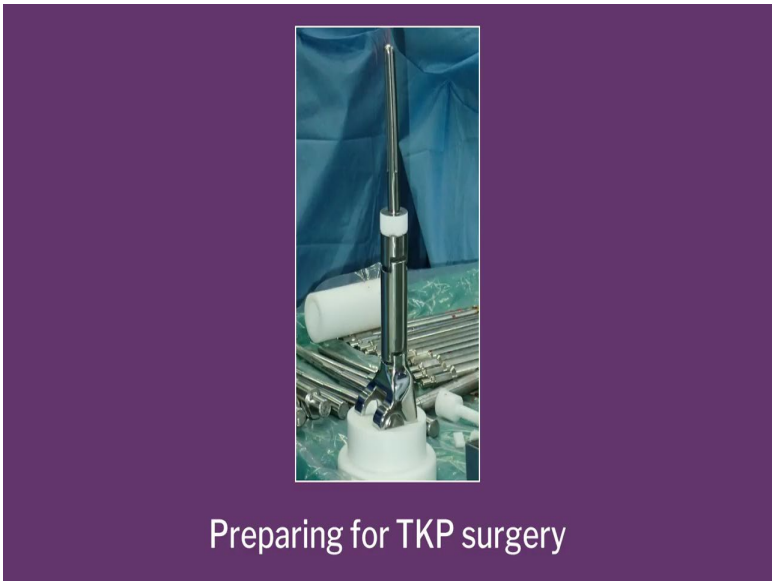

And then we actually manufactured the first lot, second lot, actual lots to put into the (patient).

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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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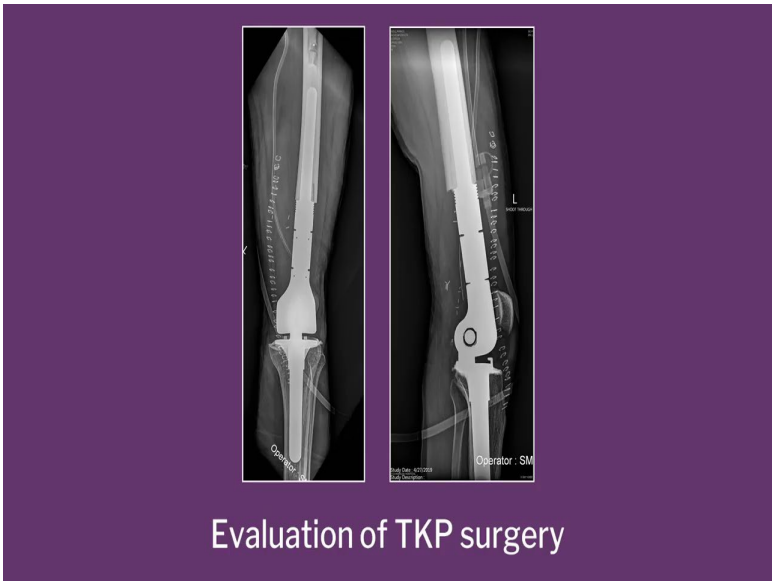

And then post-op surgery which you can see. The entire, there is no femur, there is no tibia, a part of the tibia. It's all replaced by the artificial prosthesis, right?

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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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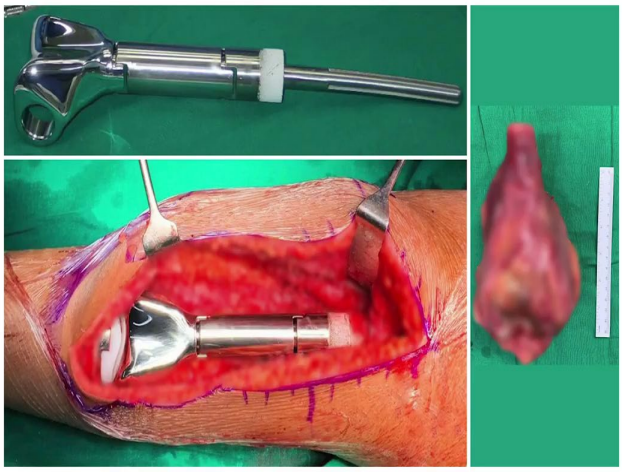

TKP Surgery - 28 May 2019

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.

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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.

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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.

Sir: So, if you can come up with a mechanism which automatically grows, with the movement is what you are talking about.
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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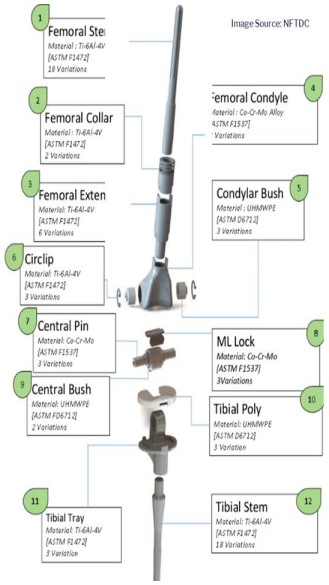

You can take this forward. So, for example, we did talk about, you know, all the aspects. How many parts are there.

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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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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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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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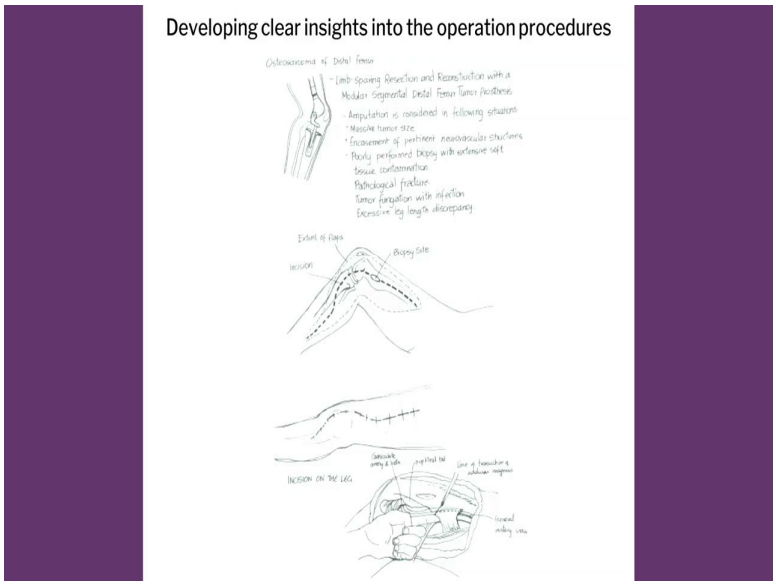

And how will you do that, so these painstakingly, you know, *Dattaram Chari*, our project associate, would sketch every component and every aspect and create a manual for the doctor. He talked about every part of the tool being used. How is the tool being used? How the armamentarium is being used? How 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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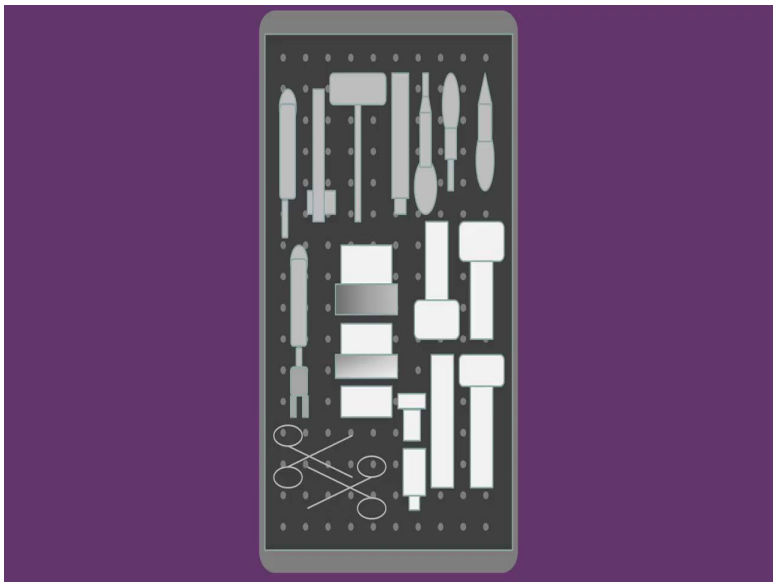

So, we have to design the armamentarium box and the packaging for our product.

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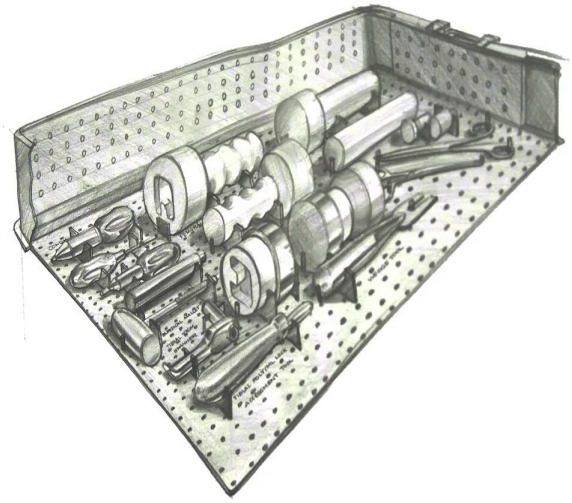

So, we studied what type of sizes we are getting. What type of components we are getting. These are the initial ideation sketches.

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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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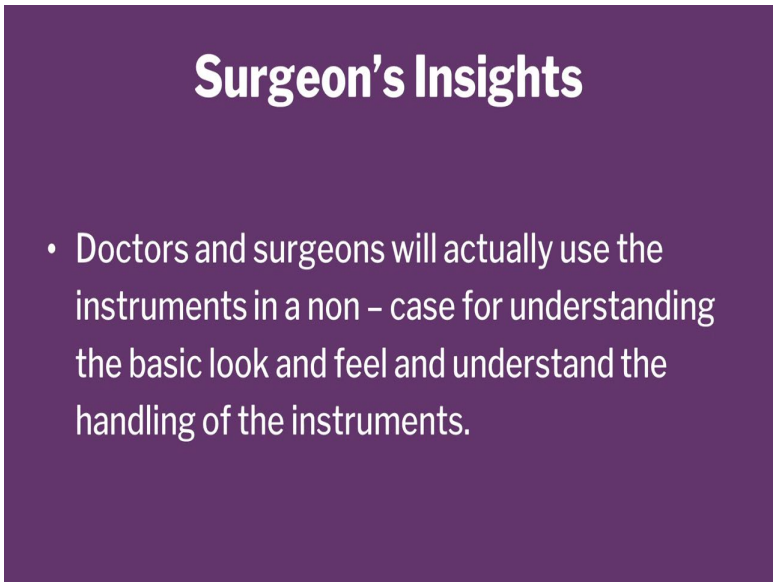

And doctors and surgeons will actually use the instruments in non-case for understanding the basic look and feel and understanding the handling of these instruments. So, for this you know what we did? We bought a mannequin, cut the leg, made holes in the mannequin and we got the doctors to operate on 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.

So, can we have one side clip rather than both sides clip? All these suggestions were coming in after you actually did something called operation using dummies.

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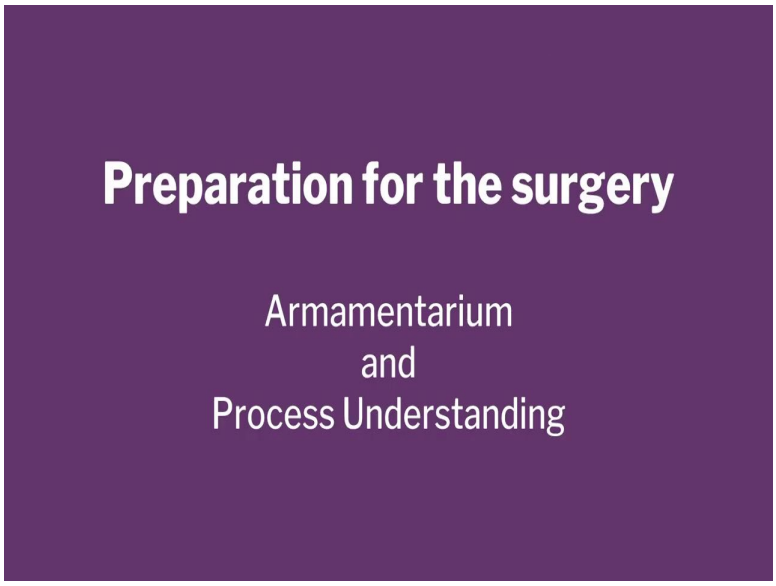

So, if now looking at the preparation for the surgery.

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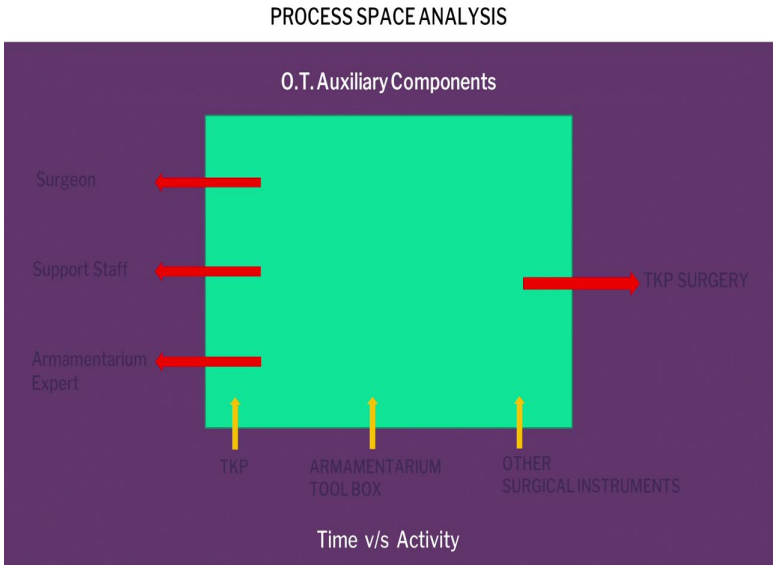

So, when you have a theater, operation theater, it is a very complex phenomenon of people around you. There are anesthetists there are, you know, multiple helps with the doctors. They have their senior doctors, there are junior doctors, there is the main operation surgery and, you know, and there are 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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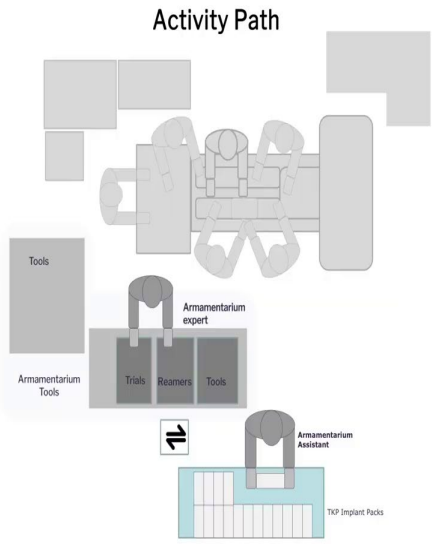

So, we were just, you know, we made all these components you see. Where all you will keep what? The tools, the reemers, that trials, the dummy trials, and then here we have the armamentarium tools. And those are how the doctors will be all around the patient to get the operation done. And there is this 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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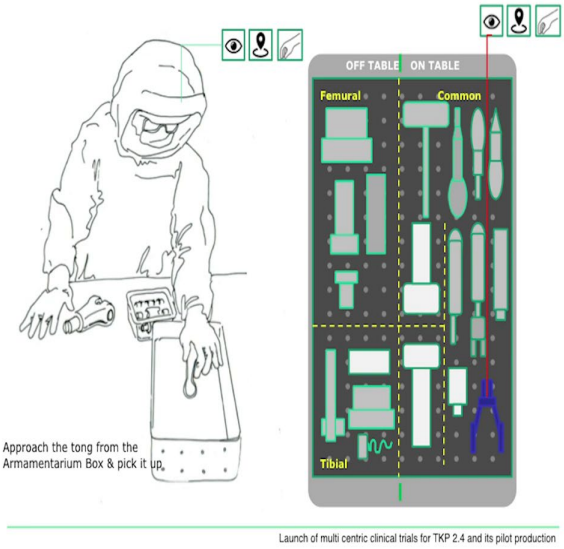

So, he made a division so that it is easy for the doctors and therefore the assistants to pick up. See how nicely it has been done.

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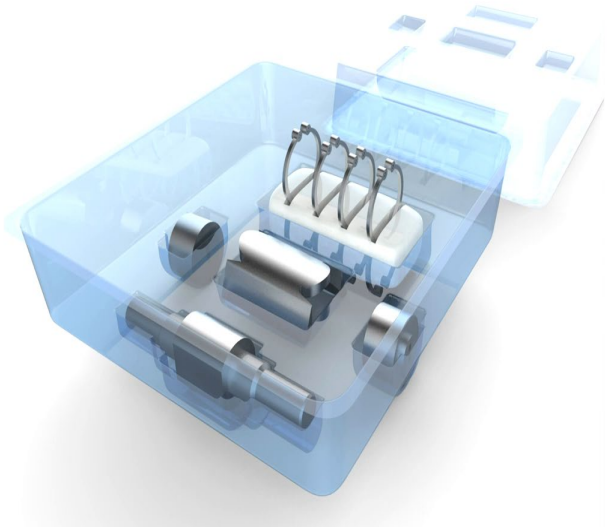

And then he packaged the product so it is easy to pick up. Look at the packaging. These are the clips which go and lock the pin which is being used and there are two extra clips if a clip falls down. It has a special tool to hold this, like this, open it, push it in and leave it. So, because it is spring-loaded 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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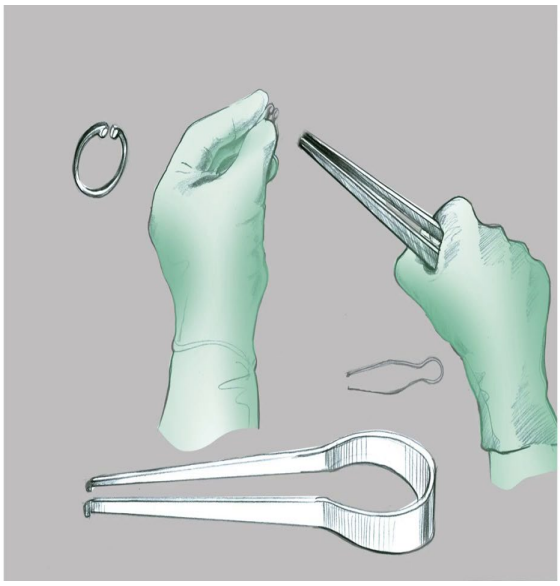

And designing of the clip holder and how it will work also is part of the armamentarium design. And we created the grips, and what type of openness we need to have, what type of profiles we need to get and all these things were done. And every part the ‘On table’ and the ‘Off table' as its each tool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

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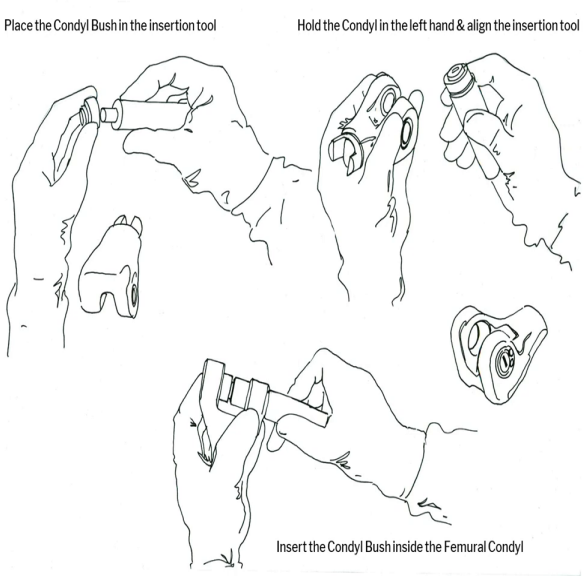

And a process was defined of what will happen. Remember there was a picture board to show the process of operation. Now there is a picture board to show how each part is being worked upon and that made it very, very easy and useful.

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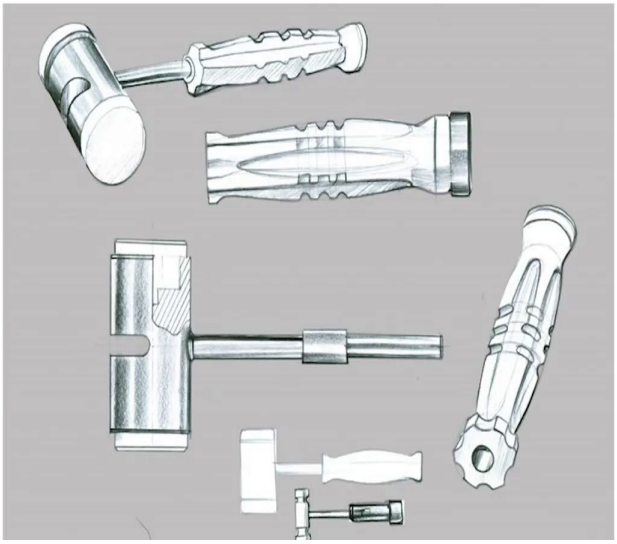

And then again the surgical hammer. What type of load comes? How heavy should we make the surgical hammer? Because you were tapping it once it can damage the whole body bone, for example, so you need to really have a very, very right type of weight for the right type of application because you are sending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

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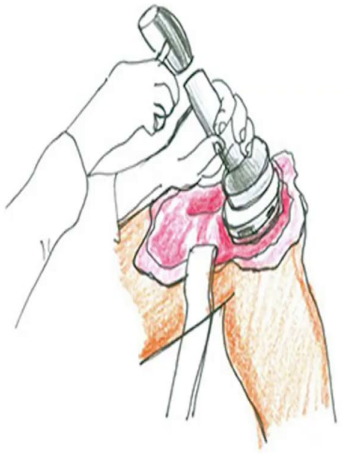

Inserting the Tibial stem

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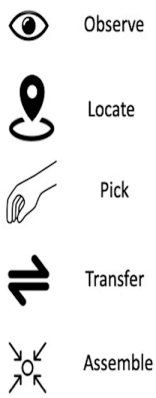

He made this, you know, aspects of viewing, locating and holding.

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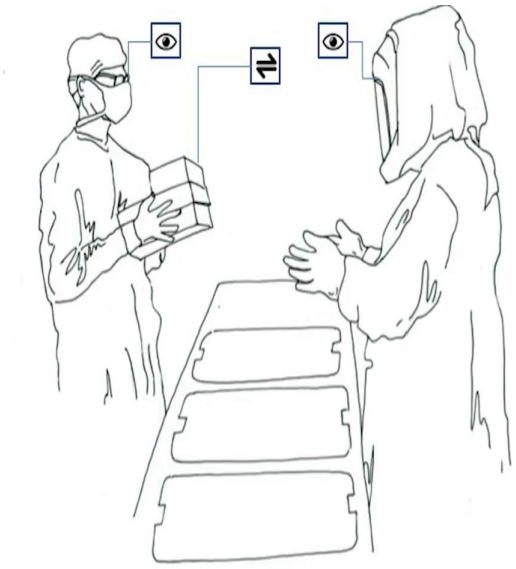

You have to see and you to pick up. For example the sizes, you do not have to catch it, you know, you just have to see the size because there is a large text over there, small, large, so you can pick up. So, this particular thing is a locator, you have to take them and pull them in the location and then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

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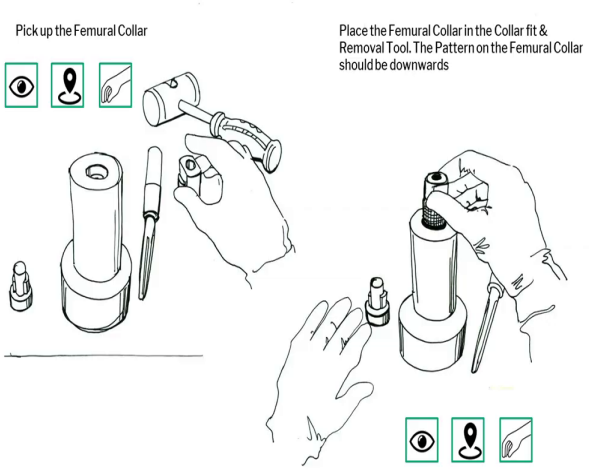

So, these are the three icons he developed to make it very clear that, which of them you are not touching, which of them you are placing the right location, which of them you are opening. See it is a very big risk if you open 3 sizes unnecessarily. You have lost the sterilization aspect. Your repacking 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,

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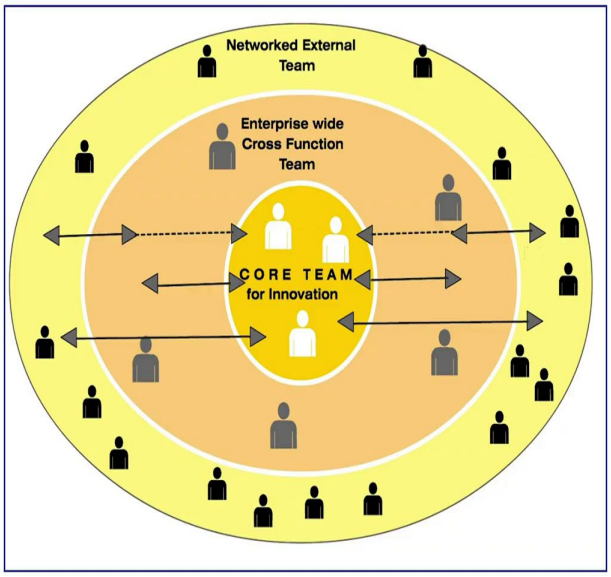

so, there is a core team. There is a support team like me. There were a lot of people in the support team.

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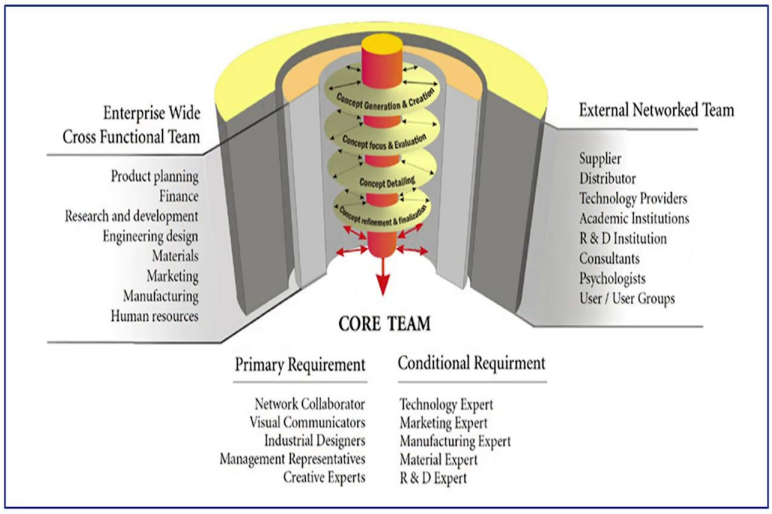

And then there was this larger enterprise-wide team. So, the teaming was very interesting here. The first team consisted of the 3 professors who work day and night and their team members, there are at least 4 to 5 team members. Prof. B. Ravi had at least 10 to 12 M.Tech students and 4 PhD students whose 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.