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

Lecture-19
Systemic Approach to Biomed Innovations Part 3

So we talked about these various 16 steps.

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One thing I want to highlight is that in all the steps, right from defining to deploying, the role of doctors is very critical. In fact, call it as Bedside to Bench to Business to Bedside, because you are identifying the need of the bedside of a patient. Developing a solution on the bench side which is engineering, but then unless you go to business you cannot deploy it, but it goes back to bedside again.

So, Bedside to Bench to Business to Bedside is a cycle for a medical device innovation. In every step doctors had to be consulted and without them you cannot succeed. Ideally multiple doctors. So what I am going to share now with you is the pipeline or the process by which we are able to do the innovation, put the resources together, and take it all the way from bedside to bedside again.

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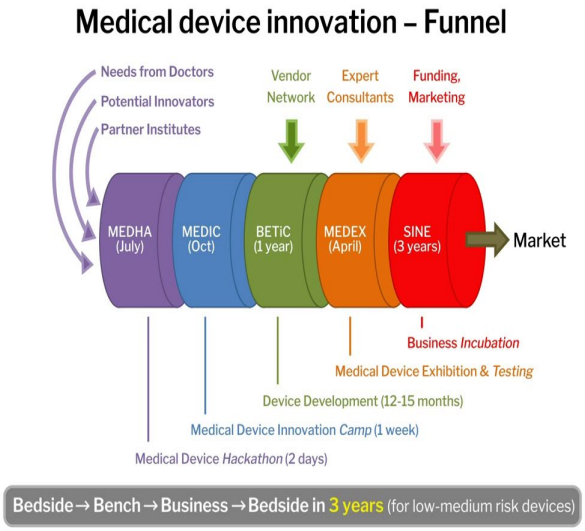

It starts from MEDHA which is a Medical Device Hackathon. What you do is, the whole year we keep getting doctors saying, 'Solve this problem, solve that problem', so we make a list of those problems. We also get a lot of applications from students or working professionals saying, 'we want to try this area out'. And third is, we have several institutions who want to initiate or start a medical device innovation cluster. So what we do is we put all the three things together and we organise a series of hackathons called as Medical Device Hackathons, which is a two day affair.

Starts on a Saturday morning and ends on a Sunday evening. And we bring those institutions, we do it some other place and those people who wanted to work in this field and doctors who said we want to take up some problems. We bring all of them together, and typically we do it in May, June, July, August months, and those who after doing that, some of the working professionals or winners of those events, MEDHA events, especially those who want to take, go forward, one more step forward. They want to equip themselves with the right kind of skills and contacts and so on.

We bring them to what is called a Medical Device Innovation Camp or MEDIC. We typically do it in the end September or early October. And this is a one week affair. So we start on a, let us say Friday evening, and of course it is a Friday morning, Friday, Saturday, Sunday, Monday, Tuesday, it goes for 5 days and five days and four nights, ok? Usually we have people not sleeping on the fourth night because they are trying to push the whole thing.

But many times it happens that people start, start losing sleep from day 1 itself. And those who withstand that training and pressure and are able to build something in 5 days 4 Nights, we usually invite them, or they usually come by themselves for a fellowship in BETIC. This is a one year fellowship, it usually sometimes extended it for one and half years, but in one to one and a half years, they are supposed to develop a complete medical device, test it in the lab, may be even preliminary testing in a good hospital and go to the next step which is put it in an exhibition. Medical Device Expo, MEDEX, Ok? So we organise our own MEDEX twice in a year.

But you also put in other exhibitions organised by our Government or private organisations. Now, exhibition what happens is, when people are coming in and saying, 'Hey, I like this device. What does it do? Can I get it? Can I buy this? Or some distributors would like to partner with you or some doctor says, 'This is fantastic, I want to talk about it or test it'. Then you start getting the validation that what you have done is something very nice.

And that is the stage when you go to the next step which is to actually start a company. What is happening is many young people start a company, then you start developing a device, then they are pivoting that is changing the Design or Market or Customers, Ok? Then trying to find partners and by that time they run out of money, Ok? Then you end up giving a lot of equity to private companies or venture funding. So it is not a, we feel a better way is to do as much as possible before.

And once you start a company, you should be able to start selling in year 1. Not developing, developing for 2 to 3 years. So typically what we say is from Bedside to Bench to Business to Bedside. We should be able to traverse the entire pathway in 3 years time for a row risk device.

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So these are pictures of the hackathons that we have done, Medical device hackathons in different places.

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They are in Bombay, Pune, Nagpur, Kolhapur, Wardha different places. We have done about 11 of those. And then we also do medical device innovation camp. The first one we did in IIT Bombay in 2015. Then we cycled it to Pune and Nagpur. Came back to IIT Bombay last year and this year also we did it in IIT Bombay. And these are all teams of 4 people. Every team has a doctor, a designer, a mechanical/electronics engineer.

And also we give them basic lectures. We give them interactions with domain experts, doctors, patent lawyers, regulatory experts. We have nightfire side stories and their stories are so inspiring

that these people wanted to actually work on devices through the night. And finally, we have a spotlight on the last day where they actually present their ideas. What they have done in 4 days and 4 nights to a jury, a room full of hundred members, top doctors and industry people, investors and so on. And usually it is a game changing life changing experience for everyone.

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So people who are working in BTech over the last 2 years, this is the current team. They all have come from previous MEDHA and MEDIC like that. So either they attend that or participate in that, they won the things. And they usually leave their current jobs and then come and join because they think this is the, they want to make a contribution, make a difference to medical device innovation.

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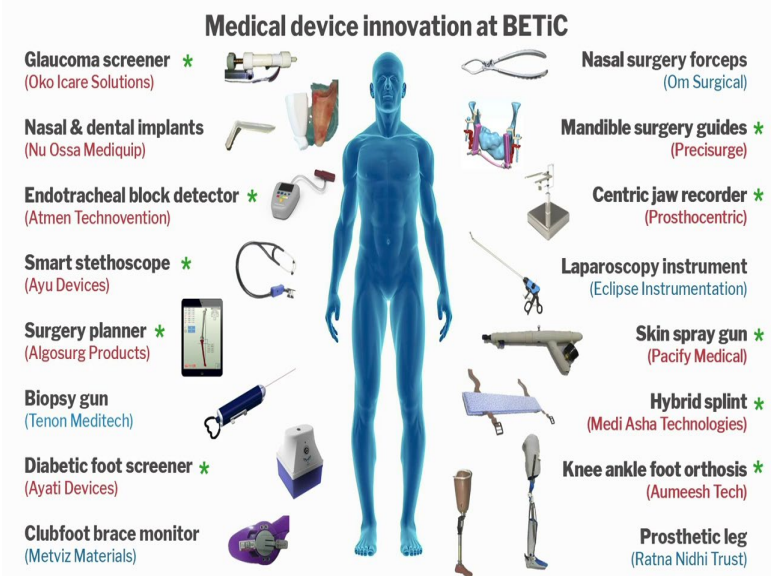

What they have done in the last 4, 5 years is amazing, about 16-20 products. You look at diagnosis, monitoring, screening devices, surgical instruments, your assistive rehabilitation devices. You literally head to toe has happened in BETiC in the last four years. And within, among them, if you have noticed, the red ones are the startup companies. There are 10 startup companies. And then there are blue ones, (which) are licensed to Indian industry. Some companies come in and agree to manufacture it and we will transfer technology to them.

Now you also see green stars. The green star is the Biotechnology Ignition Grant, or BIG Grant of 5 million rupees. 10 times Betic people have won that. Plus there are 5 more companies started by BETiC innovators, which are not in this list. So, total 15 startup companies and 5 licensed to industry. So, 20 you can say is a high impact of BETiC.

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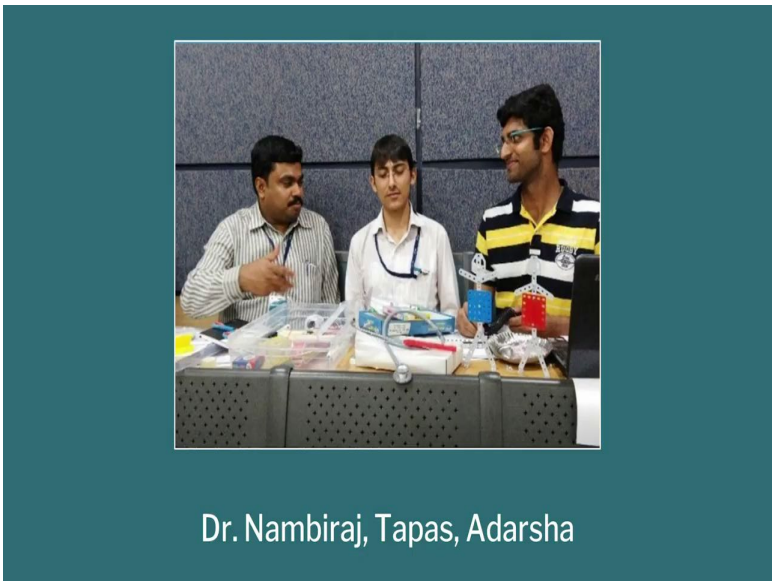

So let me give you two of the stories out of this.

The first story is the story of Tapas and Adarsha, who joined hands, at that point with a rural hospital doctor called Dr. Nambiraj. So these three were participants in MEDIC 2015. They all got together for the first time, when the doctor said that, 'When I put a stethoscope on the chest of a patient in my rural hospital and I hear an unusual sound, I do not know whether it is an emergency or not. Should I send the patient immediately to a city hospital or a district hospital or not? I wish I could somehow send the sound to my friend in Pune or Nagpur or Mumbai and get a second opinion. Remote auscultation'.

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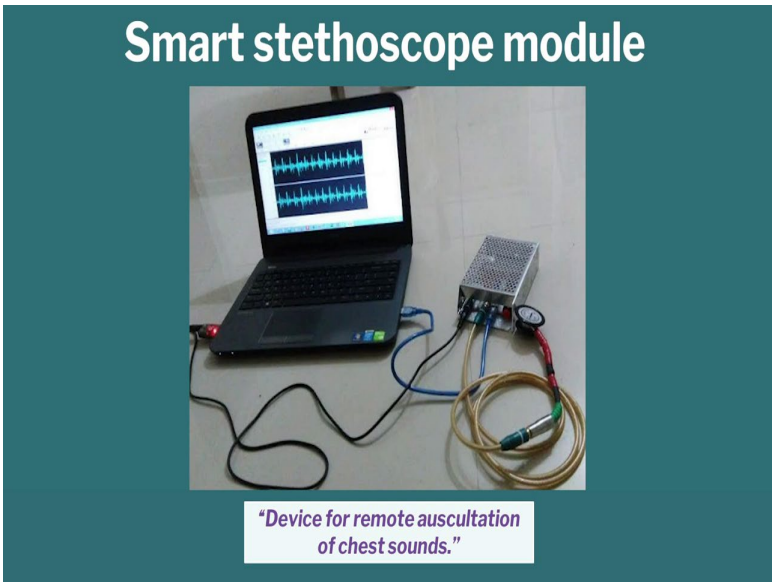

Auscultation means hearing the chest sounds, remote means hearing the sounds of a patient who is not in front of you, Ok? So can you believe that in 4 days and 4 nights these people built a prototype and Tapas was in the audience, put a stethoscope on his chest, Adharsha was on the stage and a loudspeaker, you could hear Tapas's heartbeat. So they won the competition, MEDIC competition but instead of going back to their companies, they were both working at that point of time, a few months later, they resigned from their jobs, came to IIT and said we want to take it up full-time, Ok?

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And so we put them in touch with hospitals, Fortis hospital, Hinduja hospital and so on. Within a years time they developed a proper prototype which is self-contained, ok?

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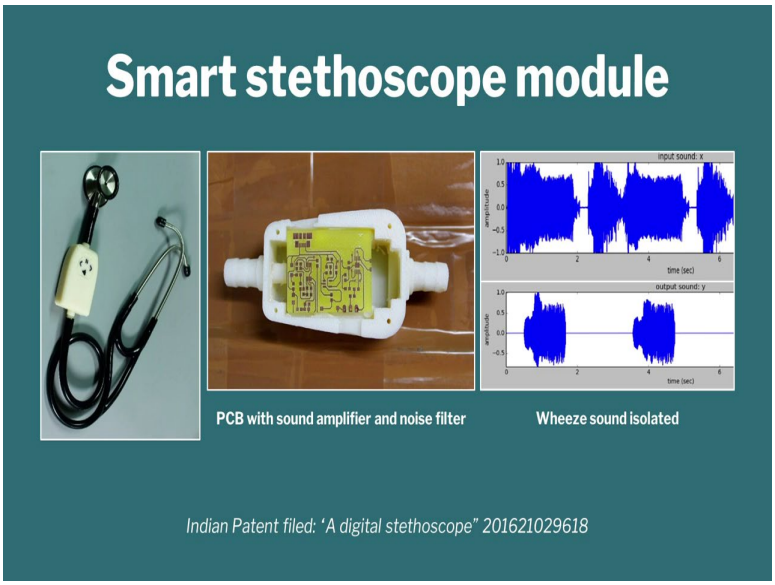

And they developed the electronic circuitry for that, to enhance sound, cancel noise. And they can record it using an output to a mobile device and of course you can transmit through mobile to someone else. So now the audio file can become part of the health record and you can see they can start doing the analytics. They can now start distinguishing between unusual heart sounds, a murmur or unusual lung sounds let say, a veeze or a cough. Ok.

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They filed a patent, they continued to work with the doctors, they applied for the BIG Grant, the won the Grant in 2017. Right after they started a company.

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Last year in December, 2018 December, they went to a rural camp where they had to screen a lot of patients for chest and heart sound and, within one year of starting a company, they had sold more than 500 units of the device. Various companies, doctors, hospitals, telemedicine companies, rural Primary Health Care Centres and so on. They are now outgoing and very strong.

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So this video shows you that, how they got together, how they worked together, developed the product, then took it to market as a startup company. What difference they are making, all this they are showing.

Let me tell you one more story like that. This is a story of multiple innovators, I am telling.

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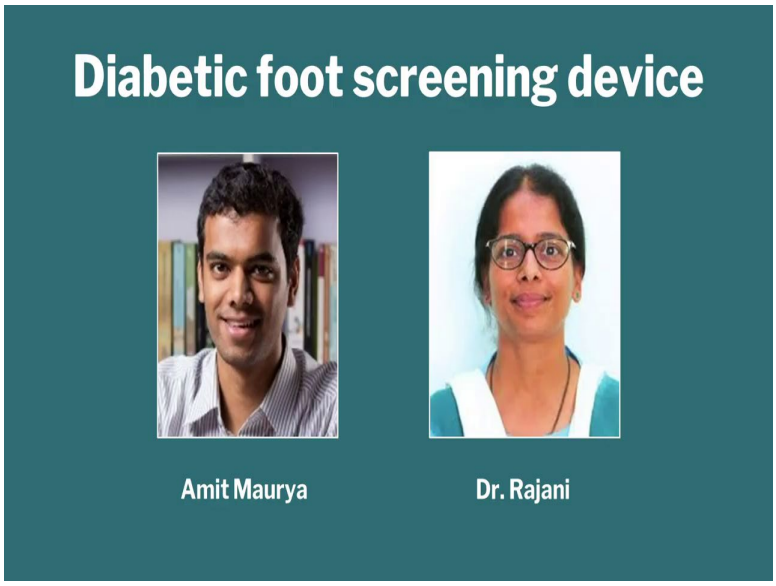

It started from one student called Amit Maurya, a Mechanical Engineer student and Dr. Rajini is the Director of Centre for Human Movement Science in MGM hospital in Navi Mumbai. So, she said that many patients come to her with what is called as Diabetic Foot Neuropathy. Now diabetes, you know, is affecting, like, 60 million people in India. In that order, more than that. And apparently 10% of them will develop what is called Diabetic Foot Neuropathy.

What it means is that the nerves and the blood vessels in the foot are now damaged, they do not work. So when one steps on a stone or damages your foot in some way, you do not feel the pain because the nerves are damaged, but it will not heal either because now this blood supply is not there.

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Ulcer

Amputation

So eventually infection becomes gangrene, gets infected and eventually the foot's are amputated.

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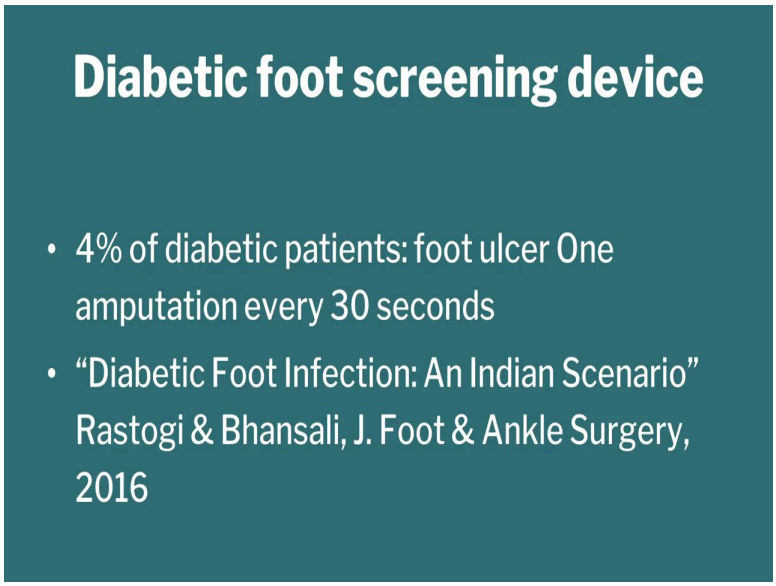

And apparently at this point of time, every 30 second someone's foot is being amputated. It could be a toe, it could be the entire leg. And remember that every half of the diabetics are in India only, or at least one third are in India. So, every minute or every 2 minutes someone's leg is being amputated because of diabetic complications. Now it is still not making it to newspapers, but it will become big headlines before you know it, ok? So the doctor told us that this is important, and we said, 'Ok, let us start doing something to prevent the amputations, by predicting that this patient is susceptible to Diabetic Foot Neuropathic condition and so a device to save the patients.

There are devices but they are cumbersome, they take time, they are subjective, it depends on the patients and doctors opinion. So we wanted to make something which is objective, scientifically works by itself.

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So, we created the first version of that, went to some hospitals and demonstrated that. The doctors gave a lot of feedback.

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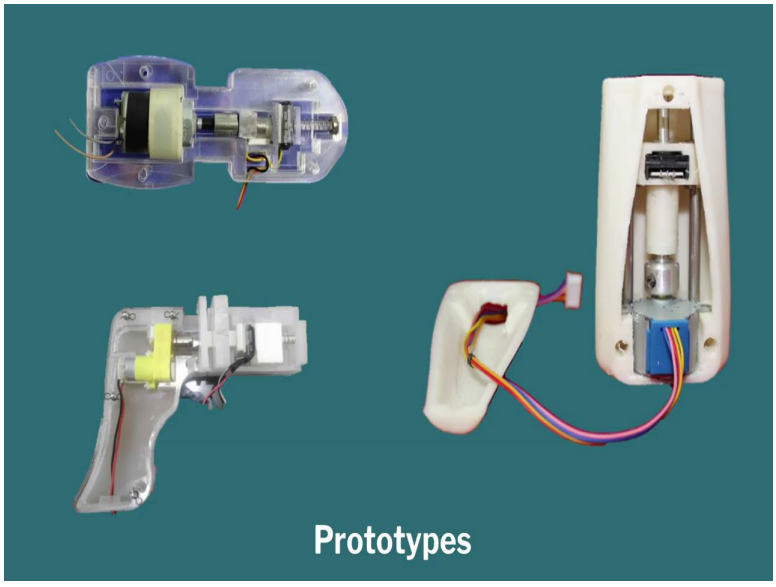

And you have version 2 and 3 and 4 and you can see, each version is different. And this student left and he joined some other startup company.

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Then we got someone else called Nishanth Kathpal, who is an electrical engineering graduate of IIT Bombay. And he took the project forward. Devised and developed a much more comprehensive, much more smarter, much more faster, device. Ok.

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He added more functionality to do the whole thing.

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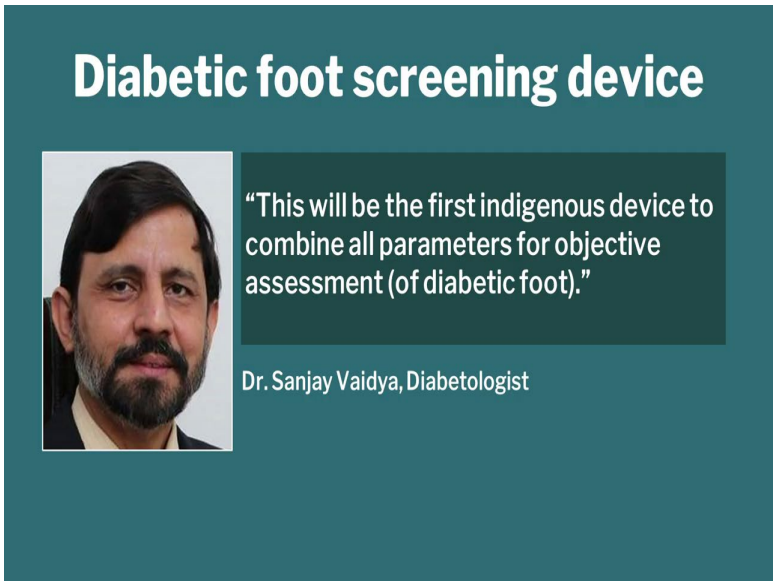

And eventually he also applied for the BIG Grant and won the award and started a company called Ayati devices.

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And recently we had also launched it in the MEDIC event with Dr. Anil Kakodkar ji and our Director Prof. Subhasis Chaudhury. And now it is making headlines. We have Times of India and other papers have covered it nicely. So, this man is now taking off on his entrepreneurship job.

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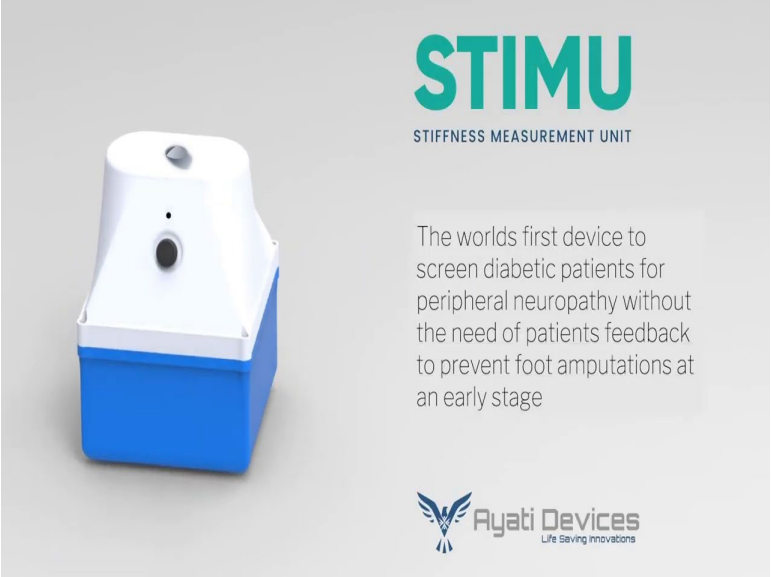

So, STIMU stands for Stiffness Measurement Unit.

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What we found is that instead of looking at just the touch and temperature sensation, what is what doctors do, we actually send a probe to find how hard or soft the tissue is? And apparently, the tissue stiffness has a very high correlation with possible diabetic foot. The entire foot can be scanned. You have special points where you can see where they have high points, that is where you need to probe and see whether that it is susceptible to diabetic for the doctor.

The whole thing can be done in a fraction of the time of what it takes by normal way of doing. And the patient can stand, does not need to be lying down and all. And he has 2 versions. 1 is a home unit, which can be used by patients or by lets say, GP's, General Practitioner Doctors and one for let us say Diabetologist or diabetes specialist. So a lot of advantages for the whole thing and this technology is now going forward to be a start-up company.

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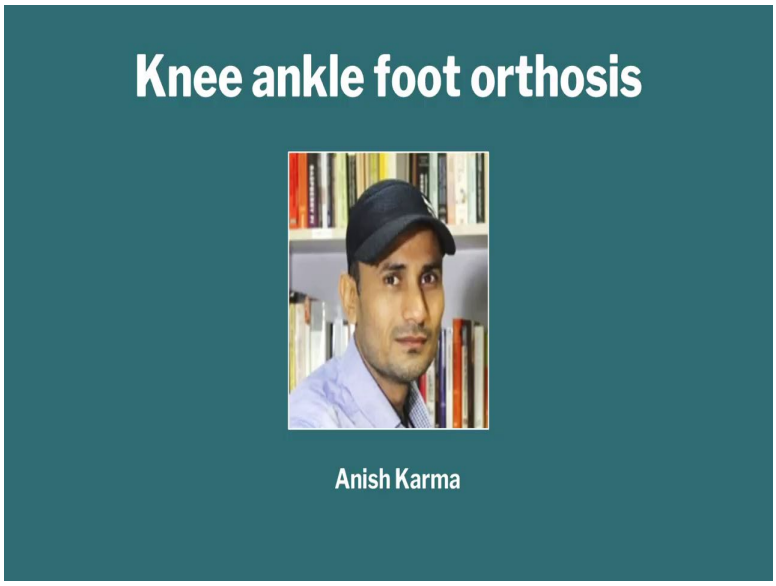

The next story I want to share with you is the story of Anish Karma, and he is a polio victim himself, and he said that when polio victims either have to place a hand (on their leg) to prevent buckling or they wear what is called a caliper, technical name is Knee Ankle Foot Orthosis or KAFO, Ok?

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Now KAFO comes in only two versions mostly. You have one low end version which is supplied free of cost to Government hospitals, which is rigid, Ok. For sitting you have to unhook the whole thing and it will dangle and you can sit down. But you cannot, even that sitting thing is only 90°, you cannot squat on the floor. You cannot cycle with that. Whereas the high end devices cost you lakhs of rupees, millions of rupees.

And those have electronics and power packs and hydraulics and so on. So if something goes wrong, you cannot use it anymore. What this man said is, ‘Can I have something in between, something which makes me walk a little more naturally, like with a knee joint and so on, and lightweight and give support, but not expensive like the high end device. So he would go to, he took free calipers from a government hospital but started going to local cycle shops, started doing welding and modifying saying that, I just, and he is not even an engineer.

He has not even passed his college exam. So he started innovating himself, eventually got in touch with BETiC. We invented him over here.

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And you can see from version 1, he has progressed to version 2 and 3 and 4, far more aesthetic, far more functional, far lighter weight, easier to manufacture, Ok? It won’t tear clothes and we are putting now, some more covering to the whole thing and so on. Now it is progressing to a stage where we can commercialise that.

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And that is the stage where he also got in touch with Dr. Rajni again, so using the Gait lab which we already have. He walked on the platform and we are seeing whether it is closer to a normal human gait or not.

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Remember this the first time he is wearing his own calipers. And remember he is walking without putting his hand and he is walking more naturally, he is not like, leg is not rigid leg. Although you can see that there is a little bit of not a natural walk but he will get there eventually.

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Then he started winning awards. Lot of awards in handicapped category, design category and he also recently got BIG award and that money has now gone to start his company, which is called Aumeesh Technologies.

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And this is again a bit of video of how the functionality of the whole thing. As you can see he is able to not only walk, he is able to squat. Look at the angle, almost close to 0 degrees. He is able to walk and eventually you will see him even cycling. So, the patient is an innovator and the innovator became the entrepreneur now. That is the story of Anish Khan Karma.

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The next story I pickup is a student from College of Engineering Pune, CoEP, and the local doctor, Dr. Ashish Ranade, he said that, 'When children break their bones in the school, you usually put a splint to immobilize that until they go to hospital. But imagine that happening on a highway or in a farm.

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So we have to immobilize the hand until you go to a hospital and then they will put a pastor. So you need something in between before you put a plaster. That could be for even for a few hours or for a few days. How do you solve the problem?' So what he came up with is that he said, 'I will make a hybrid splint'.

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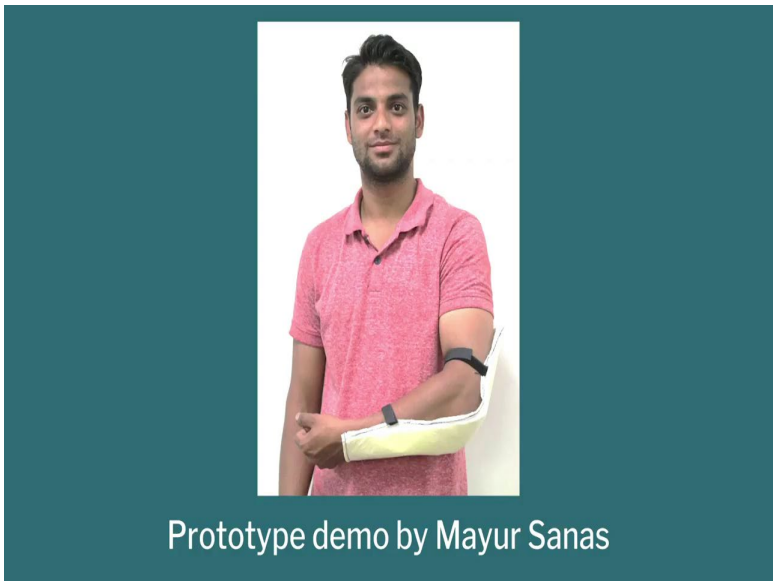

It is made of a combination of materials: paper and plastic and tissue and cotton and so on, and you dipped in water, you shape it around the zone where the fracture is there and within minutes it becomes rigid or hard in the air. So it becomes like a splint and you can now go to hospital. It will hold your hand until you go to hospital.

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Again he has gotten very good responses from potential partners, distributors and so on. One distributor is actually speaking to them as we speak to take it all over the country. He is looking at designing machines to make it rapidly, at low cost. So, imagine that it can be deployed in every hospital, every school, every sports facility, wherever there is a possibility of fracture occurring.

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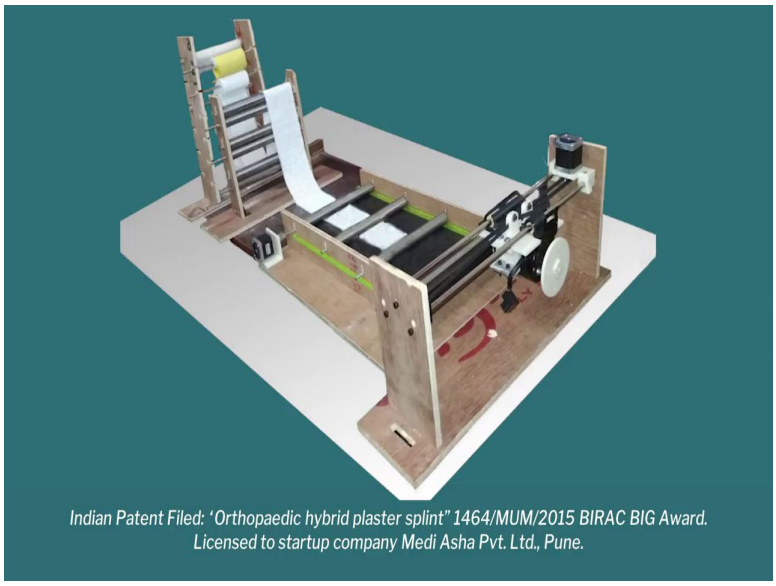

Indian Patent Filed: 'Orthopaedic hybrid plaster splint" 1464/MUM/2015 BIRAC BIG Award.
Licensed to startup company Medi Asha Pvt. Ltd., Pune.

He also got a BIG award. He also filed his patent and a patent is licenced to his own company, which is called as Medi Asha company.

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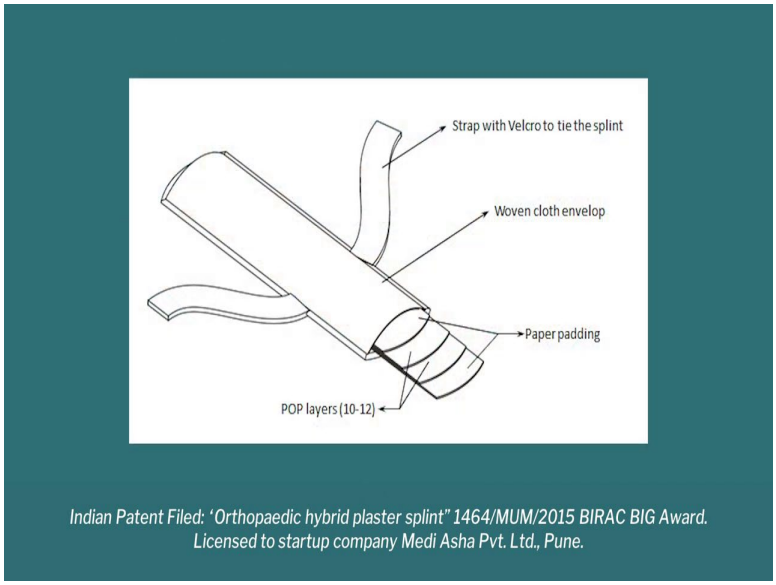

Indian Patent Filed: 'Orthopaedic hybrid plaster splint" 1464/MUM/2015 BIRAC BIG Award.
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Two more stories I will tell you which one of them is an instrument. I have been talking about diagnosis and treatment and assistive devices, but what about surgical instruments.

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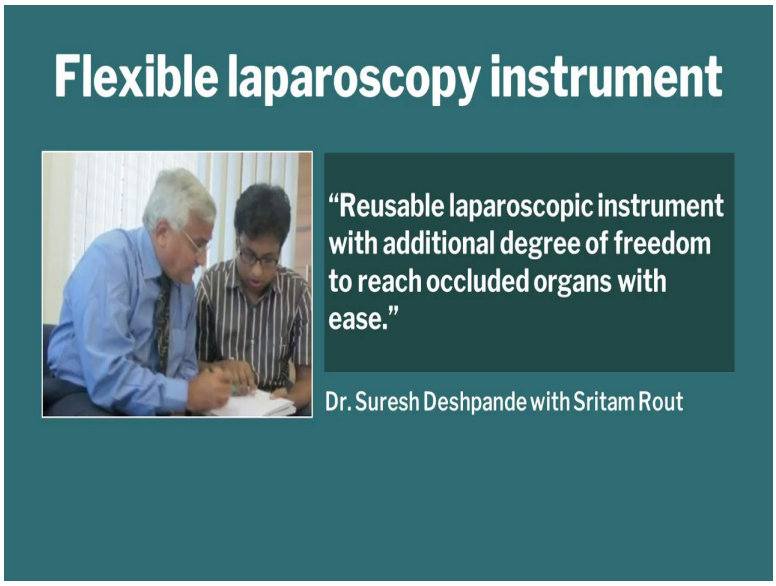

This is one story of Sritam who is from IIT, who later on went to Johns Hopkins and now is in a US company, but when he was here for 2 years, he worked with one doctor called Dr. Suresh Deshpande. Suresh Deshpandey has trained thousands of laparoscopic surgeries. Laparoscopic surgery is that if you have anything in your abdomen, could be appendicitis or gallbladder or kidney problem, whatever, instead of making a big cut they can just send an instrument through the navel, small cut. And through the instrument they can do surgeries.

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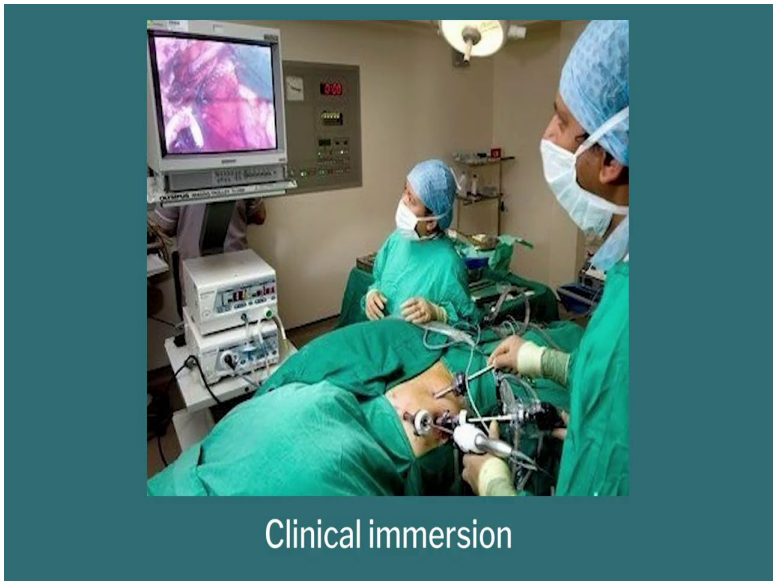

Now, because now you are not doing with your hand you are only holding a handle and the surgery is happening at the end part of the handle, imagine that. At the end part there is only 1 degree of moment. It can either grasp it or cut it. But what if you want to suture? Not possible, very difficult.

So what the doctor said is, ‘Can you give me a wrist at the end of the instrument? Can you make the instrument have more degrees of freedom?

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So, Sritam started with that. Initially it was a paper concept, literally. And then 3D printed concept then metal prototypes.

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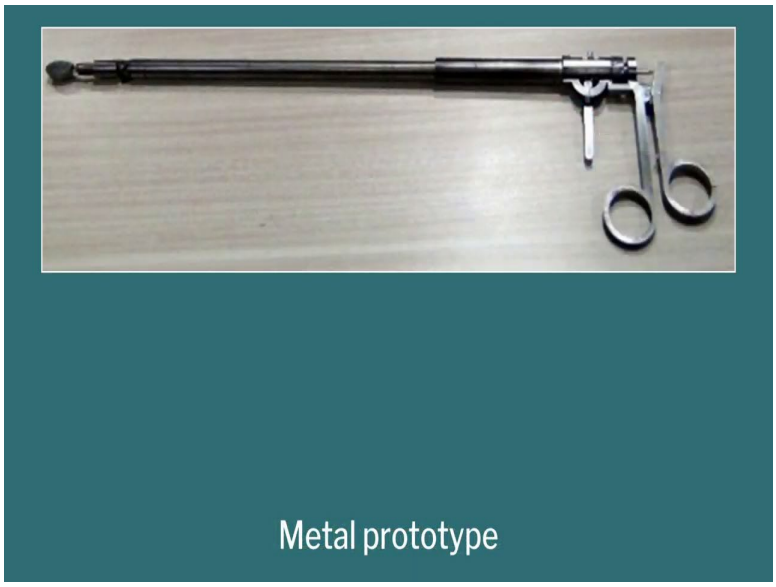

Metal prototype of different categories. Finally he went to a stage where the device could be demonstrated.

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And making these metal parts was a big nightmare for us. Very fine metal parts, and the doctor said, 'I should be able to sterilize equipment again and again and reuse that'. And sterilizing means you cannot have wires, the wire will become loose. So all are rigid links and how we develop that is a mystery. Development and manufacturing is a big challenge and fortunately a company came forward called Eclipse Instrumentation in Thane, and they said that, 'We were looking for something like this to commercialise and take it forward'.

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So they licenced the technology. We have given the whole details, the drawings, the bill of materials. How to make it? All the training for them. We have helped them to make the first few batches of the parts and then they are gearing up for mass production and marketing of the device. So this is one more example of an instrument.

One last example perhaps I want to give is a biopsy gun. Whenever there is a tumor in the body, you want to know whether the tumor is benign or malignant. Ok.

And so what you do is the tumor is somewhere inside the body, somewhere inside, you want to, you cannot, you want to take a sample to test it. If it is malignant and you remove the entire tumor but benign you can leave it on. Generally the body will take care of itself.

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Now you need a sample of the tissue. That is done using what is called a biopsy gun. You send a needle inside the body and it will suck out or cut out a piece of tissue, bring it out safely and put it under a microscope to check whether it is malignant or benign. Now the thing is the existing device is for single use. You use the device, get the sample and throw the instrument out and bill something 3000 or 5000 rupees to the patient. What doctor said is, 'Why am I wasting the instrument? Why cannot I reuse the instrument? Why can't I just throw the needle and the needle can be made for just 100 or 200 rupees'.

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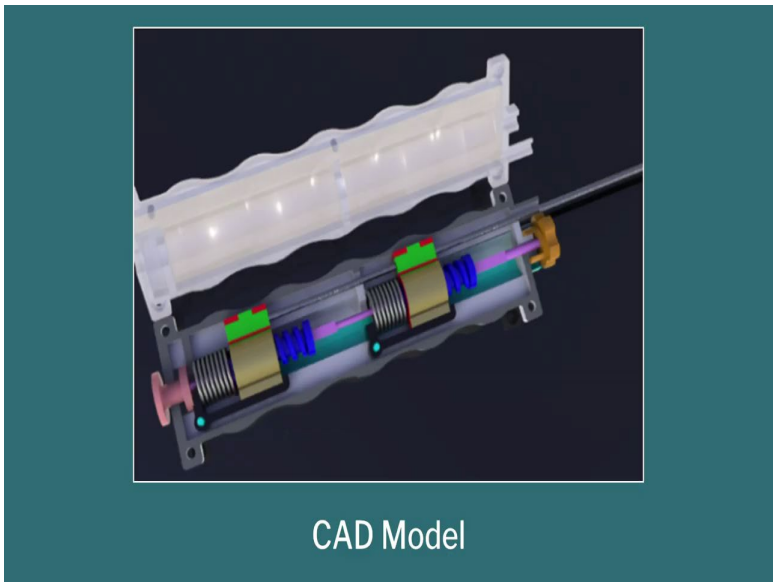

So he started on the journey. He made the first device. They can see how the design is changing through the CAD model to Physical, first prototype, second prototype, third prototype. Made more easy, more economic, more easy to adjust, handle all those things.

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And again one more company called Tenon Meditech in Pune, they came forward and said that, 'We want to licence the device and we want to do mass production'. They were already looking for developing something like that. Fortunately, we had developed already. So they joined hands and whatever we developed, we gave to them and after that they are modifying it slightly more with our help only and then it will be ready for mass production and marketing.

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So as you can see these stories are part of a larger Canvas of doctors working with engineers. And these are all our happy pictures. Most pictures will have doctors and engineers and some pictures will have patients also. The MEDEX exhibition. Exhibition is very, very important for us. It is an acid test to know whether this device should be commercialized or not. Final acid test. Put on an exhibition, all stakeholders, distributors, doctors, patients, possible patients, investors, all are coming there.

If they show a lot of interest then you know that it is time to start a company and we have done 15-20 of our own exhibitions and we have put in exhibitions of other organisations.

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And exhibition will also mean press coverage. So we have had press coverage in all the major national mainstream media and also on social media. We have online media, we have TED Talks, we have things like Forbes India, Business Outlook. So we have covered fairly well. What it does is that, one it gives an incentive to the innovator himself or herself, which is like an incentive. It is like they feel good that, 'Ok I have done something which is valuable and interesting to the society'.

Number 2 is, it attracts potential partners, doctors, investors, distributors and so on. In fact the first order for the Stethoscope came from an IAS Officer in Gujarat who read the article in Business Outlook or Forbes magazine, and he read that and made a phone call saying that, 'I heard about it.

Can you come for a demonstration?' So we get contacts through, sometimes through media outreach like that, so it is very valuable to have a media presence in a nice way.

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And also the stories of the medical devices innovated at BETiC, 16 stories of them, along with 16 steps which I talked to you about, those 16 steps, all illustrated by 16 stories are there in this book called The Essence of Medical Device Innovation. And also the best practices of every step, I mentioned to you that we have standard operating procedures, we have forms, we have records, all these things are now being captured in what is called an ISO 13485. It is like ISO 9001 for medical devices. Far more difficult than ISO 9001, but we finally got a certificate for BETiC.

We got the verification, surveillance audit was also done successfully, so we are now authorised to develop medical devices. And what the certificate means is that we are doing it in a systematic manner. Anytime anyone wants any detail, there is a written record of how we have done, what we have done and why we have done something.

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And today BETiC is no longer one centre in one place. We, as I mentioned to you earlier, BETiC was earlier established in three places, immediately after IIT Bombay, VNIT Nagpur and College of Engineering Pune. But right after that in the last 3 years. We have had four more engineering colleges, K J Somaiya College in Mumbai, MIT Arts and Design Technology University in Pune, Symbiosis International University in Pune, G H Raisoni College Nagpur, these 4 also set up their own self sufficient BETiC cells.

We also have now 5, 6 hospitals. Plus we have an agreement with SINE, IIT Bombay, Venture Centre in Pune, An agreement or arrangements so that these innovators can start companies in these incubators. And various Governments also take our help to create the Innovation and Entrepreneurship ecosystem in those things.

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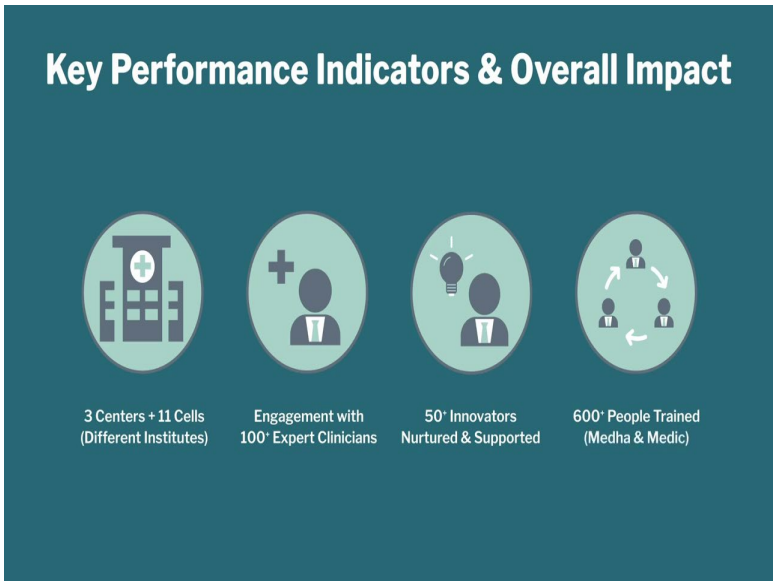

So, if you look at the overall summary of what we have achieved so far, we have now 14, 15 centres, we have more than hundred doctors who have continuously engaged with us. More than 50 innovators who have gone through the process, BETiC fellows who have invented something. Many of them have either licensed the technology to a company or to their own startup company and therefore we have like a startup company. More than 600, 700 people trained through MEDHA and MEDIC, so they now know medical innovation.

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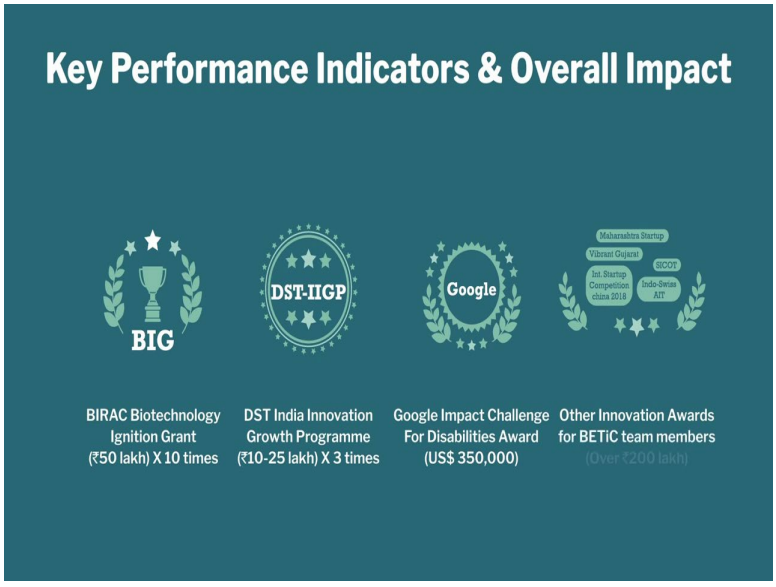

BIG awards (was granted) 10 times. Similarly, there is another big award called DST Lockheed Martin, India Innovation Growth Program gold medal, that we got 3 or 4 times. And then Google Challenge award and many other awards which are not even counted, but that is not a happy thing.

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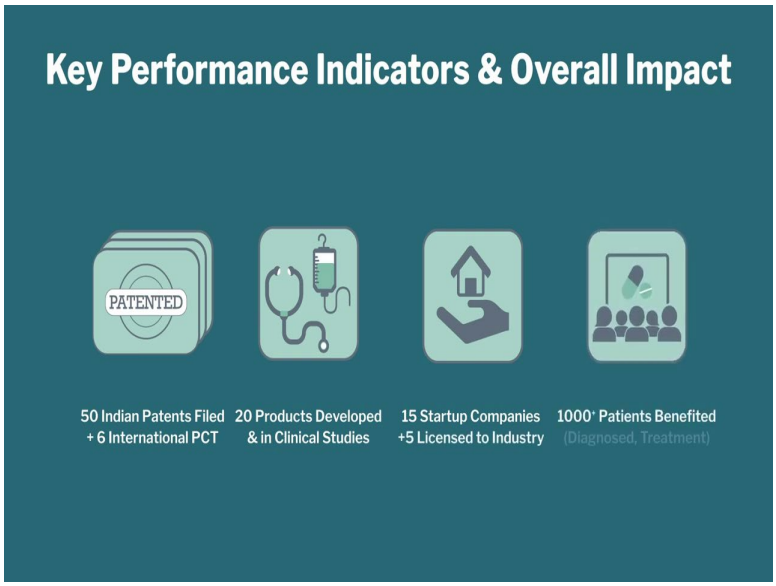

The real happiness comes from the fact that we have a technology created and IPR rights secured, patents filed, 50 patents filed and 6 filed internationally, 20 products developed, 15 startups and 5 licenced to industry and more than 1000 patients, and this number is going very rapidly now, who have been touched and benefited by these devices. So the question now is: How did it happen? What is a secret ingredient or secret sauce for the whole thing? When people ask these questions we try to boil down to something which is easily understandable and implementable also.

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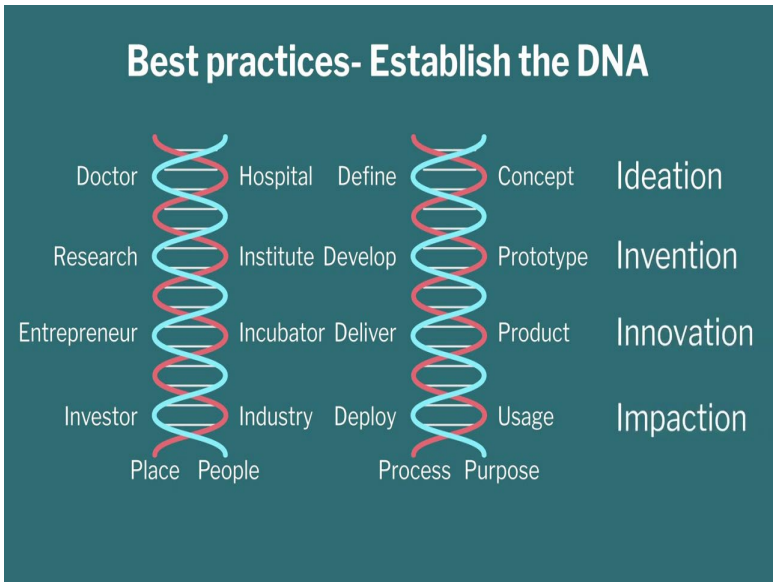

So we say that the DNA of medical device innovation has 4 strands. 1 strand is of people: The doctor, the researcher, the entrepreneur and the investor. The place stand: doctor in a hospital,

research in an institute and so on. And then the two other strands are the process strand: Define, Develop, Deliver, Deploy. And then the purpose or the outcome strand which is: The first one is concept, second stage is prototype, third stage is where you get a product and the fourth stage is where you get an application of the product in the market, usage. We call this as Ideation, Invention, Innovation and Impaction axis.

Ok that is the DNA of the medical device innovation ecosystem as implemented in Betic. The other secret sauce is that we need to create the right kind of a facility. One is hardware, equipment. You need prototyping in plastic and metal and electronics and software, that definitely you will need. And ideally if it's certified, ISO 13485 or ISO 9001, it is great because your systems are in place.

Second layer is about the people in the centers. You definitely need people of different disciplines and branches, because innovation requires collaboration between different disciplines, I have been telling you that, so you need that. And ideally visitors and faculty and experts and technicians, all coming in, you need all kinds of expertise for that. But the most important thing is a culture part of it, and I want to highlight once again that innovation is driven by collaboration. Collaboration means going out of your comfort zone. And that means reduced ego. That is possible when you focus on the end user which is a patient in this case.

A patient in suffering, a patient in pain, if you keep that in your laser focus, that laser focus gives you the energy to go out of the comfort zone and do something wonderful.

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I will end with this last slide by saying that finally if you want the right results in life, it is applicable to anything of course, but if you want the right results in life, you have to put in the right action. Right action comes with the right vision. Vision is a very dicey thing, very difficult to grasp. But the easier way to understand is that, if you have the right intentions, you will automatically have the right vision. If you have the right vision, automatically you will have the right action. If you have done these three things right, you do not have to worry about results in any case. Life will be ok. Thank you very much.