

## Hot Start-up: Crafting bioabsorbable implants for India

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PLA is a biodegradable biomaterial made from corn, sugarcane or sugar beets, widely manufactured in the United States.

The biomaterial instantly attracted Dr Lele's attention due to its unique properties including being able to be absorbable inside the body and retaining the mechanical properties to a certain time period.

He then introduced this product to Dr V Premnath, another chief scientist at NCL, who has his PhD from the world-renowned Massachusetts Institute of Technology (MIT). Dr Lele holds his PhD from the University of Delaware, USA.

The product was promising and was sufficiently challenging to stir the enthusiasm between the two, and before long, they teamed up together to develop biocompatible maxillofacial volume filling implants.

Four years later, in 2010, Mr Piyush Joshi, a polymer engineer from the University of Pune, joined them. His expertise helped them to identify the benchmark properties of the product to-be developed, and its economics.

They soon realized the importance to make bioabsorbable polymers with varied properties. All the efforts by the team were directed towards synthesis of appropriate molecular weight PLA material.

The three of them participated in Venture Center's (Pune) 'Lab2Mkt' program which focuses on commercializing early-stage technologies.

The idea bagged its initial funding of Rs 7 lakh from proof-of-concept (PoC) initiative. Thus the team were able to raise a small amount to setup initial experiments to synthesize the bioabsorbable polymers, and carry out further market research.

With sustained market research, the trio understood that this single product will soon envisage the whole product portfolio using bioabsorbable polymers and their composites.

By 2012, they went on to study and identify other products which use similar polymers.

"There were no Indian manufacturers who made biomedical grade PLA, and this was a real setback for the Indian medical device manufacturers. Surgeons had to rely on foreign players. We saw this as an opportunity and decided to use the expertise to develop the bioabsorbable materials and products for India. This was the moment when the idea was taking firm roots to be considered as a platform to create a new venture," says Mr Piyush Joshi, COO and executive director, Orthocrafts Innovations.

Over the next two years, the whole team was building the chemistry know-hows of medical grade PLA, and was waiting for the appropriate funding opportunities.

Mr Piyush highlights, "The opportunity struck us when BIRAC announced BIG grant funding scheme. We realized that this will be an excellent opportunity to bring our efforts to fruition. Post our participation, BIRAC approved our concept."

Post which, Orthocrafts Innovations was incorporated.

Dr Ashish Lele (48), and Dr V Premnath (45) serve as the [start-up](#)'s director and advisor respectively.

So far, a capital of Rs 20 lakh has gone into the company.

Mr Piyush believes that materials development for biomedical applications is the company's niche, and will transform medical device industry by slashing the time taken to develop products along with the costs.

He adds, "We plan to capture the value in development of biomedical grade polymers which are suitable for implants, and downstream products using the same. We plan to work closely with Indian medical device users to develop newer products. Our ability to tailor materials and making them suitable for product development is the biggest strength."

Mr Piyush recalls that the path was not simple during the beginning days. "Lack of ready infrastructure, non-existent dialogue between product users and product developers, lack of access to crucial raw materials, were the most common hurdles," he comments. "One of the great challenges we faced was to identify and execute suitable technology transfer model from NCL. Thanks to the team at NCL innovations for their prodigious efforts and continued support, Orthocrafts today enjoys necessary technology rights for material and product development."

In its initial days, the venture also faced issues with putting the required resources such as skilled manpower, equipments and funds.

However, the major challenge was in terms of taking the business idea from ideation-stage to the prototype-stage through the existing ecosystem.

"There were hurdles in terms of setting up right mechanisms to transfer technology to the [start-up](#), uncertain possibility of scientists participating in a start-up, and scarcity of scale-up funding from ideation-stage to first prototype," remarks Mr Piyush.

Orthocrafts is unique in terms of a company structure, where Scientists from CSIR (Council of Scientific & Industrial Research) are allowed to take equity and be a promoter of the company.

Orthocrafts is amongst the first few [start-ups](#) where CSIR's 'Scientist Entrepreneurship Scheme' has come to fruition.

"So far Orthocrafts is successful in setting up a new trend among scientists, who now are thinking of shifting from traditional technology development, and transfer model," Mr Piyush points.

It aims to aggressively grab opportunities to work with surgeons and hospitals to cater to their needs.

Considering India's growing potential in medical tourism, the [start-up](#) will focus on multispecialty hospital chains in tier-1 cities. It also plans to establish connections with surgeons in tier-2 and tier-3 cities to increase its impact.

Moving ahead, Orthocrafts intends to develop its portfolio of products by expanding into new biocompatible bioabsorbable materials such as PDLA (Poly D-Lactide) and PCL (Polycaprolactone). It is also looking forward to collaborate with institutes with strong programs on tissue engineering.

"We also aim to develop next level of downstream products such as suture anchors and tacks for hernia repair. The company will also focus on building a strong IP portfolio for these materials and products as we go ahead," he shares.

Its efforts will also be focused on getting products through pre-clinical and clinical trials to secure necessary approvals such as USFDA and CE mark, accompanied by ISO 13485 and ISO 10993 certifications.

Orthocrafts visibility strategy includes an active website as an initial communication channel.

Besides this, it also participates in various programs organized for the medical devices fraternity. "We intend to participate in various business plan competitions to improve the company's visibility," Mr Piyush opines.

He also says that the Indian government has taken deliberate efforts in fostering entrepreneurial culture.

"As a result of this, we see a revolution in the software sector. Indian government is taking giant efforts in replicating similar models in the biotech sector. However such efforts will come to fruition only when the youth of this country are encouraged to participate in new business ideas. Having supporting activities for entrepreneurship at undergraduate level will certainly help create more entrepreneurs in the country," he elaborates.

He continues, "Today, only a handful of investment opportunities are available in engineering and the biotech sector in India. Bridging this gap will help flourish these sectors. Easy availability of risk capital at idea-stage will be of most use. I strongly believe that the government has taken steps in various efforts such as BIRAC and MSME. However, accelerated program execution will be a key to success."

He notes that in the West, the economy is mainly focused on R&D intensive businesses and products.

"India still emphasizes on service-based approach. Western countries have influenced policies, education system and financial markets to support [start-ups](#) as they see [start-ups](#) as economic growth engines. I would like to acknowledge here that sustained efforts for decades have helped Western countries to develop required entrepreneurial ecosystem," he says.

Faster business processes, ease of winding [start-ups](#), availability of risk capital at very early stage, and strong technology pipeline from educational institutes have given unprecedented advantage to Western countries.

"Similar model may not be suitable for India considering the vast needs of Indian population," Mr Piyush suggests. "However, India has embarked its footprints on global map through frugal innovations, maximization of resources, business model innovations, and workflow innovations."

As a trend in the medical devices industry, he expresses that many people are choosing in-house design and development as a main stream activity.

At present, the product development emphasis is mainly on medical electronics and instrumentation.

He also reveals that there are many emerging opportunities in making customized products for patients where start-ups can venture into.

He considers Pune as an upcoming start-up hub apart from Bangalore and Hyderabad.

"Pune has rich history of entrepreneurs, especially big business houses such as Bajaj and Poonawala group among others. Pune also has a strong educational system which provides skilled manpower for start-ups," he validates.

The 30-year-old entrepreneur stresses that India is now seeing a steady growth in VCs who are venturing into the Life Sciences space.

"However, the approach is more towards safeguarding the investment rather than risk-taking approach. Long gestation period for products increase the risk in Life Sciences-based start-ups," he explains.

"For shareholders and investors who are looking at immediate returns, Life Science start-ups would be bad proposition," he mentions. "By the time these companies reach pilot scale, huge investment would have already been made and that increases the ticket size for such investors for far less equity. Also if joining the journey at late stages might lead to reduced returns. I believe that indexes such as GREX index is one of the most innovative way of raising start-up funds."

As for Orthocrafts, one of the biggest challenges will be to navigate through the almost non-existent regulatory system in the

country. "We also envisage that acceptance of products amongst the medical fraternity will take some time, but we wish to deliver a world-class innovation at the disposal of Indian surgeons. While we face strong competition from current foreign players in the Indian market, we are optimistic that we will be able to penetrate through the market," Mr Piyush says confidently.

Mr Piyush counts patience and deliberate sustained efforts in achieving goals as the two most valuable qualities of being an entrepreneur in the field of Life Sciences

He advises that for Life Sciences-based start-ups, joining an incubator or an accelerator is the best starting point. "Such premises brings supportive infrastructure at very lower costs. It also provides important connections to like-minded people," Mr Piyush says, for whom Ratan Tata had been a big role model.

Entrepreneurs are human too. They undergo insurmountable stress at times. "There are a number of occasions where I feel highly stressed. In such situations I prefer to take a walk while listening to my favourite music by A R Rahman or Yanni. I also find that watching Tendulkar's batting as a great source of relaxation," he states.

The entrepreneur also enjoys reading, music, movies, adventure sports, finding new food joints, and loves exploring vacation spots.

"Entrepreneurs should not hesitate to take risks, pursue a lot of networking, and choose products carefully. Last, but not the least, always aim high," Mr Piyush ends, who says that he would have ended up being a mechanical engineer developing cars for F1 had he not been an entrepreneur.

#### **Quick Bites:**

##### **Entrepreneurial Mistakes to Avoid:**

- i,§ Choosing inappropriate team, especially co-founders
- i,§ Lack of clarity on regulatory pathway
- i,§ Failure to sign right agreements or contracts with employees, vendors and others
- i,§ Failure to file strategic IPs

##### **Entrepreneurial Lessons Learnt:**

- i,§ Highly essential for co-founders to work in coherence in clearly defined roles
- i,§ Choosing products wisely
- i,§ Not wasting time once the goal is clear
- i,§ Choosing funding partners carefully with due diligence
- i,§ Never hesitating to take risks