

A matter of the heart

The story of India's successful artificial heart valve provides many lessons in technology development.

Gathering and coordinating a team of medical men and clinicians, veterinarians and toxicologists, biomedical engineers and materials scientists in the quest of a manufacturable biomedical device is no mean task. In the case of the artificial heart valve, success was imperative from the point of view of India's medical needs. Along the path to the final product were numerous problems, both peculiar to this project and of the type that confound any such venture.

I remember meeting Dr Valiathan for the first time at the dreary old dormitory in Rafi Marg where CSIR employees who came to Delhi could stay. Dr Nayudamma (then Director-General, CSIR) had suggested that he meet me because I too was interested in materials and biomaterials. Valiathan, an expert heart surgeon, had been Hunterian Professor of the Royal College of Surgeons, and a colleague and collaborator of Hufnagel, the great pioneer of heart valve prosthesis. He had come back to India voluntarily with an intention of serving here, and was working in the emergency ward of Safdarjung Hospital! With a sparkle in his eye he asked me, 'Is it not time we produce heart valves in India for we need so many of them?' For hours we sat on the uncomfortable cot and he talked. He told me of his dream of having a heart centre and his fervent desire to see that a heart valve was made in the country.

There was no doubt in my mind that he would succeed, not just because he would have access to some of the newer technologies that a few labs in India were working on—new materials, unconventional fabrication methods and surface-modification techniques—but because of the intensity with which he felt that the Indian heart valve *must* be made.

Two decades have passed and finally he *has* succeeded. The first Indian heart valve prosthesis is now a fact. The country can truly be proud of this achievement. His Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), where he slowly gathered a multidisciplinary team of clinicians, toxicologists, animal experts, engineers and scientists, can also be proud of what has been done. Valiathan and his institute deserve our congratulations.

Eschewing the tendency of most R & D institutions to keep their work secret and to hold their cards close to their chests, Valiathan considered this a national project and cast his net far and wide for solutions. This little device—the cardiac valvular prosthesis—weighing less than 5 grams is a thing of beauty, representing the best in materials science and modern technology. The list of materials used or tried reads like a 'Who's Who' of advanced materials; a staggering array of frontline technologies had also to be pressed into service. As a sampler one may mention titanium, 6Al4V titanium alloy, chrome-cobalt alloys, polyacetal, Ekonol, supertough Delrin,

single-crystal sapphire, partially stabilized zirconia and ultra-high-molecular-weight high-density polyethylene (UHMW-HDPE); and 3D pantographic milling, electrical discharge machining (EDM), EDM die sinking, conventional computer numerical control (CNC) milling, CNC wire-cutting EDM, electrochemical milling, electron-beam welding, ion implantation, physical and chemical vapour deposition (PVD and CVD), powder metallurgical techniques, electrocomposite deposition and laser polishing.

At one stage the project was beset with what appeared to be insurmountable difficulties. In those dark days there were even murmurs of the project being abandoned. But with Valiathan's never-say-die philosophy the institute surged ahead in a totally new direction that culminated in the clinical model, which is now undergoing controlled human trials. The artificial heart valve was implanted in the first patient in December 1990. Yes, it has taken almost 12 years to evolve it. We should congratulate the project leader G. S. Bhuvaneshwar for his tenacity and persistence in the face of so many odds and criticism.

This issue carries an article by Valiathan (page 77) on this development. The article is written in his characteristically modest style; and yet he has not been able to suppress the excitement he and his team felt in this endeavour. A. V. Ramani, who till recently led the Biomaterials Technology Wing of Sree Chitra Tirunal Institute and whose engineering intuition and skills also played a major role in the final success of this venture, provides a commentary (page 73).

I was privileged to be both a witness to and a participant in (in a small way) this saga. I feel that it behoves me to sound a note of caution. The institute cannot rest on its laurels. They say the last mile is the longest, and only when the Chitra valve reaches the common man through a regular manufacturing unit can we really consider the exercise a success. The institute has had a successful record of transferring its technologies (e.g. its blood bag) to industry. In the case of the Chitra heart valve it must choose the technology recipient with great care. Since this technology is much more difficult the recipient team must work in close collaboration with the institute on the one hand and the users (i.e. surgeons, hospitals, etc.) on the other and produce enough Chitra valves for multicentric trials. Here one is happy to note that the institute has a novel and innovative Technology Proving Facility, which is used for transferring technology to industry. We hope that manufacture of the Chitra heart valve will start by 1993 and that the valve will reach the thousands of poor Indian heart patients who have been craving for comparatively inexpensive heart valves.

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