Apr 29th, 1:00 PM - 4:00 PM

Paper Session III-C - Outer Space to Inner Space: The Story of the Transfer of NASA Exclimer Laser Technology to Medical Angioplasty Projects

James B. Laudenslager
Advanced Interventional Systems, Inc.

OUTER SPACE TO INNER SPACE: THE STORY OF THE TRANSFER OF NASA EXCIMER LASER TECHNOLOGY TO MEDICAL ANGIOPLASTY PROJECTS

James B. Laudenslager, Ph.D.
Advanced Interventional Systems, Inc.

The transfer of the NASA/JPL technology started with a phone call from three physicians at Cedars-Sinai Medical Center (CSMC) in Los Angeles in the fall of 1983. The three physicians a surgeon, Dr. Warren Grundfest and two cardiologists, Drs. Frank Litvack and James Forrester called me in a serendipitous manner. They were calling local institutions to inquire about the availability of excimer laser technology to continue experimental studies they had started at CSMC and then continued with Argonne National Laboratories in Illinois. They were looking for a site in the area to continue their experiments on excimer laser ultraviolet radiation to ablate coronary blockages in the heart. CSMC was funded to do research by the NIH and later through private donations from hospital support groups. After discussing their ideas, I suggested they visit me at NASA's Jet Propulsion Laboratory (JPL). I immediately notified our biomedical program manager at JPL, Dr. Ed Beckenbach, to inform him of the meeting. At the meeting the physicians went over their current results and presented their proposed plan for collaboration. Since my group had pioneered the early development of excimer lasers and had several home-built as well as commercial excimer lasers, Dr. Beckenbach thought that this could be an ideal collaboration. Dr. Beckenbach went back to NASA Headquarters and discussed the proposed collaboration. He then notified us that, if we wrote a short proposal, we could obtain funding from the NASA Technology Utilization Office. The proposal was submitted and Dr. Beckenbach provided a discretionary charge number to begin collaboration until the proposal was formally approved and funds sent to JPL. Thus began a two and one half year collaboration between NASA, JPL, CSMC, and the NIH to study laser tissue interactions to define a suitable laser angioplasty system.

Initial work was to reproduce the early CSMC experiments of excimer laser radiation on tissue both free beam as well as through fiber optics. Since excimer laser technology was relatively new and not user friendly, we studied various other laser types in the ultraviolet as well as other wavelengths. But again and again whether the laser was pulsed or had wavelengths with better ability to transmit through readily available fiber optics, the use of the JPL magnetically switched 308nm pulsed excimer laser provided superior results in ablating most coronary plaques. Our NASA patented magnetic switch technology, originally developed to increase reliability for future space applications of lasers, proved to be a key technology in allowing us to design the longer pulse duration necessary to facilitate fiber transmission to make the delivery of this wavelength practical for medical applications.

Dr. Beckenbach reported on the laser-tissue ablation results from this project to the NIH and CSMC had a press release on these laser-tissue results in the Tuesday science section of the New York Times. The news story of the dramatic difference for this laser technology as applied to the problem of coronary disease, the leading cause of death in the United States, had immediate response from many unique sources. Several news media sources such as Good Morning America, Nightline, Forbes magazine, and the White House generated follow-up stories. This forced the project into the public eye with the often asked question of when will this technology be ready for humans. This question then led to the next stage of this project,

The sudden press coverage gave rise to several inquires from venture capitalists to become involved with the project. However, after several meetings it was clear that they were not interested in pursuing high risk technology but just the concept to make money on what was then a high glamour project. The research group of physicians and scientists, however, viewed the success of this project to be based more on further technical and medical development and we believed that easy solutions would not be successful for laser angioplasty. Therefore, we politely rejected their offers and decided to carry the development to humans through continued NASA and the NIH funding.

The next stage of research was to use a long-pulse width magnetic switched laser with fiber optic delivery in an animal model which had to be carried out at the hospital. CSMC raised private money and sent it to JPL to build a research laser for the hospital under contract. This project was co-funded by NASA Technology Utilization money

and NASA OAST funding for basic laser R&D for future remote sensing with excimer lasers. However, upon return from a summer vacation, I was informed I had lost my regular NASA laser R&D funding and the money from CSMC that was provided for JPL was sent to NASA Headquarters and was subsequently impounded with the next fiscal year money since Congress had not yet passed the new budget. Upon receiving this news, I immediately began a two fold effort to retain employment: first I tried to restore my NASA funding and 2) I began, in a parallel effort, seeking a means to continue the medical laser project outside of NASA. However, these events severely impacted the progress of the CSMC laser project to begin testing in animals, the next step before human trials.

The technology transfer effort consisted of presentations to venture capital firms, the generation of a business plan and a proposal to NASA for an exclusive license to the laser technology which Dr. Thomas Pacala and I had patented during our NASA research. Dr. Pacala and I were granted by NASA an exclusive license on one issued patent and granted options for an exclusive licenses for two pending patents with the ability to delay payment of any fees for a two year period to raise money for a business. Juggling the NASA funding from two separate NASA agencies and the CSMC contract became a full time effort leaving little time to work on the actual engineering development. Therefore, after several stops and starts, it became apparent that this project had to be moved to the private sector. With funding of $250,000 from a private investor, Ray Williams, I left JPL and co-founded Advanced Interventional Systems (LAIS) in the fall of 1986 and attempted to raise sufficient venture funds to carry the project to human clinical trials. The NASA/JPL laser was delivered to CSMC and LAIS after receiving four million dollars on December 31, 1986, converted this laser into a package suitable to begin human trials.

The next step was to obtain FDA approval to begin clinical trials, to develop a commercial medical laser system and to develop suitable coronary catheters. This project required subsequent rounds of financing to complete these tasks. Finally in 1991, we had enough data to submit an application to the FDA for product approval and commercialization. After a lengthy review process, the excimer laser angioplasty system was fully approved on January 31, 1992, right after a successful public offering for LAIS to raise additional money to begin commercialization of the product.

The results of this project have been very encouraging as we have been able to treat, to date, over 5,000 difficult coronary cases with success rates of 90% . A good fraction of these cases had no other option or would have needed expensive and traumatic by-pass surgery. The laser technology developed under the NASA program was one of the key technologies that allowed us to produce these successful results and to become the first company to receive FDA approval for a laser coronary angioplasty system where many other companies which went before us had failed. I believe one of our company's key advantages was the access to the NASA technology and the technical discipline instilled in us by working at NASA to do the job right.