Development of Endovascular Surgery: Experience at UCLA, 1985–1990

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In this paper, the development of endovascular surgery at the University of California at Los Angeles (UCLA) between 1985 and 1990 is described. Experience with atherectomy began in 1985 with studies using the Rotablator. After encouraging animal and cadaveric studies, atherectomies were performed in patients. However, in a subsequent multicentre trial, the long-term patency rate was disappointing (47% at five months, 31% at 12 months and 18.6% at 24 months). After experiments with laser recanalisation of atherosclerotic arteries using an argon laser indicated that it caused extensive thermal damage, it was concluded that the argon laser had limited clinical application. The need for a method of imaging the results of endovascular procedures was recognised at an early stage and purpose-made angioscopic equipment was developed. Although this equipment allowed direct visualisation of luminal topography, it led to over-treatment without producing improved long-term patency. In 1988, intravascular ultrasonography was introduced, which could accurately identify pathologies but was cumbersome in practice. During this time, we developed several models for evaluating endovascular devices and training surgeons, including the gelatin arterial support model and the UCLA endovascular training model. These allowed operators to gain experience with endovascular devices in a surprisingly realistic fashion. Experience has tempered the initial optimism regarding the potential of endovascular surgery. Research efforts are now focused on addressing the problem of restenosis. Recent technical advances include endovascular grafting for abdominal aortic aneurysm, ultrasound-guided balloon angioplasty and laparoscopic surgery for aorto-iliac disease, but it will be three to five years before the true value of these procedures is known. (*Asian J. Surgery 1996;19(1):11–18*)

Atherectomy

In July 1985, we became interested in pursuing less invasive methods of treating vascular disease. Our initial search led us to David Auth, an engineer at the University of Washington, who had recently developed a high-speed rotary device, now called the Rotablator (Fig. 1). On examining a crude prototype of this device, we were impressed by its simplicity and, in particular, the principle of octagonal displacement of friction and differential cutting of hard objects, i.e. calcified plaques (Fig. 2). We felt that this device merited further investigation and development for animal and human applications.

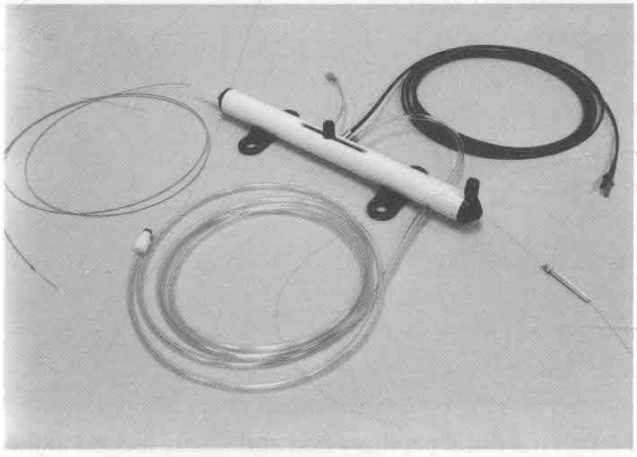

Figure 1. Rotablator atherectomy device.

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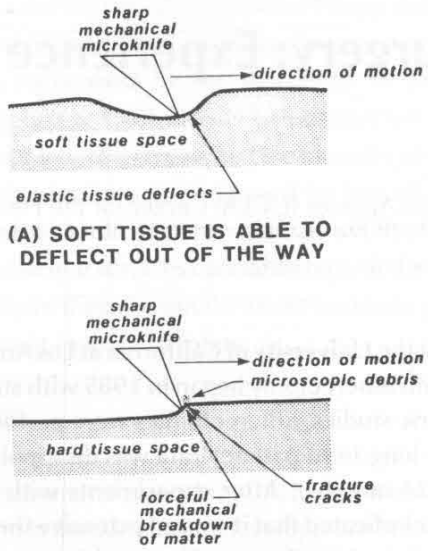

Figure 2. Diagram illustrating the Rotablator's differential cutting in soft and hard tissue.

Initial experiments in diseased human cadaver arteries were successful in demonstrating the efficacy of the device. During these first experiments, the term "atherectomy" was coined to describe this new procedure which removed obstructing atheroma from diseased arteries using a mechanical, catheter-deliverable endarterectomy device.

Between September 1985 and April 1986, the device was tested in numerous femoral, popliteal and tibial arteries of fresh human cadavers or amputated lower limbs obtained from the UCLA Medical Center and the Sepulveda Veterans' Administration Medical Center.[1] Overall, recanalisation was successful in 95–100% of stenotic arteries, in harvested as well as intact whole cadaver arteries, but in only 56–62% of occluded arteries. We were impressed by the lack of perforations, due to the differential cutting of hard plaque, and by the smooth, highly-polished intraluminal surface without flaps and dissections (Fig. 3).[2] The atherectomy device pulverised atheroma into fine particles of around 5–10 μ in diameter.[1] Further tests showed that these particles, when injected into the common femoral artery of dogs, passed through the distal capillary bed and finally lodged in the liver, lungs and spleen, the reticuloendothelial system.

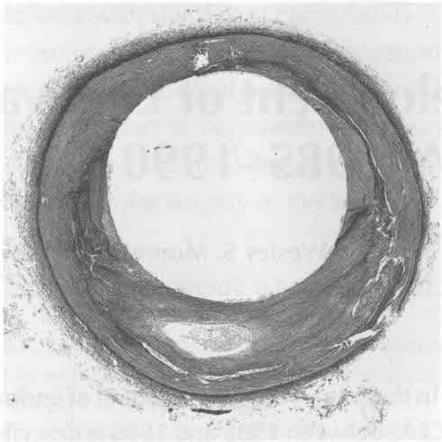

Figure 3. Cross-sectional photomicrograph of a successfully atherectomised vessel lumen. Note the smooth, highly polished, intraluminal surface denuded of intima and endothelial cells. (haematoxylin & eosin; x 40).

None of the animals developed clinical ischaemia or any adverse effects from these particles. During this time, the atherectomy device underwent 19 major modifications.

We reported these results to the scientific community and the Food and Drug Administration (FDA) and, in February 1987, the FDA approved our protocol to perform atherectomy procedures using the Rotablator in the superficial femoral, popliteal, tibial and iliac arteries of patients who were otherwise candidates for a bypass procedure. A multidisciplinary team was assembled, including Larry-Stuart Deutsch, an interventional radiologist, Lawrence Yeatman, an interventional cardiologist, David Auth, the inventor of the device, and the authors, vascular surgeons. Between August 1987 and October 1989, this team treated 20 patients who underwent atherectomy in 25 limbs and 42 arteries.[3] Technical success was achieved in 92% of the limbs and 93% of the arteries. However, there were early thromboembolic complications in 20% of these cases, and long-term 24-month patency was a disappointing 12%.

To obtain more meaningful data from a larger number of patients, we collaborated with Montefiore Medical Center, New York and Stanford University, Palo Alto. This Collaborative Rotablator Atherectomy Group (CRAG) combined all clinical data of peripheral atherectomy performed by surgical groups in the USA.[4] The analysis revealed an initial success of 89% in 79 limbs and 77% in 107 arteries, but a poor late result of 47% primary patency at six months, 31% at 12 months, and 18.6% at 24 months. We concluded that rotary atherectomy provided very limited benefit in the treatment of peripheral

arterial occlusive disease, and subsequently abandoned the procedure.

Laser Applications

In 1985, we conducted a survey among the UCLA surgery faculty regarding their interest in laser research and development. This survey indicated a strong clinical and research interest in lasers and a need to consolidate personnel and equipment. With political and financial support from the department chairman, Eugene Stern, a Laser Committee was formed to set safety guidelines, credential laser proficiency, provide training programmes, centralise laser equipment and resources, and stimulate cross-specialty collaboration. This collaborative effort facilitated the subsequent acquisition of abundant laser equipment for the Surgery Animal Research Laboratory, the Outpatient Surgery Center and the Main Operating Room at UCLA.

Collaboration with Eric Fonkalsrud, Chief of Paediatric Surgery, and Harvey Zarem, Chief of Plastic Surgery, studied the potential applications of laser welding to perform intestinal and microvascular anastomoses. With US$ 60,000-worth of CO_2 microvascular laser equipment donated by Bio Quantum Technologies (Miami, FL, USA) and a Basic Research Science Grant from the Medical School, microvascular welding of rabbit intestines, mesenteric arteries and veins was performed. Mesenteric vessels were successfully welded but adequate seals for intestinal anastomosis were not achieved. Also, laser welding was effective only in vessels of diameter 1 mm or less. Larger vessels did not weld well and either leaked or ruptured. Laser anastomosis of diseased human cadaver arteries were uniformly unsuccessful and demonstrated markedly decreased tensile strength compared to sutured anastomosis. Furthermore, the laser anastomosis took considerably longer to perform than hand-suturing anastomosis. Because of these limitations, we concluded that laser welding would not have practical clinical applications. In 1988, we terminated these studies. Interestingly, Rodney White at Harbor-UCLA Medical Center continued to pursue clinical applications of laser welding for arteriovenous fistula anastomosis.[5]

In 1987, Trimedyne Inc. (Tustin, CA, USA) provided an argon laser and metal thermal probe (Fig. 4). This device had been used to recanalise occluded atherosclerotic arteries, particularly those that were difficult to cross with guidewire and balloons. However, our preliminary experiments indicated that laser recanalisation caused extensive thermal tissue damage, and clinical results from other institutions[6-9] revealed a high rate of perforation and early restenosis. Also, similar thermal recanalisation could be achieved without a costly laser by simply heating a metal olive-tip with an electrocautery unit. Thus, we concluded that recanalisation using the Trimedyne hot-tip had limited clinical application and provided no advantages over current technology.

During the later months of 1987, Douglas Murphy-Chutorian, a cardiologist in Palo Alto, and Walter Mok, a physicist, contacted us regarding a directed "smart" laser system that they had developed to ablate atherosclerotic plaque. Their MCM company (Mountain View, CA, USA) manufactured this laser system, which used a unique computer-based programme to fire laser energy when abnormal atherosclerotic plaque was detected but automatically shut off when normal arterial wall was detected. The idea was that this laser would safely provide a central channel through occluded arteries which could then be completely recanalised by balloon angioplasty, atherectomy, or even a larger debulking laser probe. We were intrigued, and convinced our medical centre to purchase a unit and fund a Cardiovascular Laser Center. In June 1988, clinical trials began and, over the next year, 12 patients were treated. However, the overall results were worse than those of percutaneous transluminal angioplasty (PTA) alone and other investigative centres around the country reported similar suboptimal long-term results with high initial failure and complication rates.[10] In 1989, we abandoned this project.

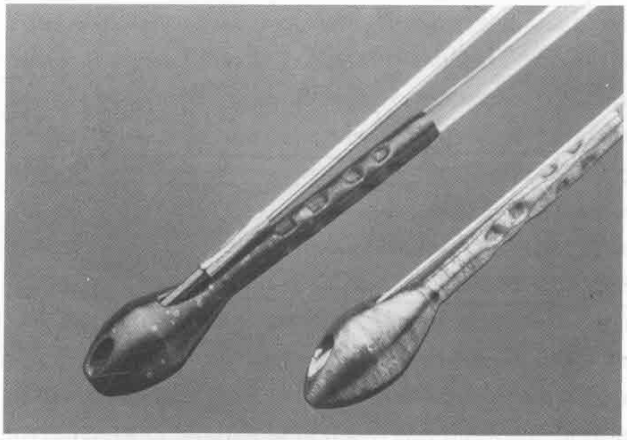

Figure 4. Trimedyne-hot tip laser probes.

Endovascular Imaging

Angioscopy

Very early in the studies, we recognised the need to adequately image the results of our therapeutic interventions. Initially, we borrowed various pieces of endoscopic equipment from colleagues in other subspecialties, such as paediatric bronchoscopes from pulmonary medicine, flexible ureteroscopes from urology and choledochoscopes from general surgery.[11] We also obtained various grabbers, cutters and shavers from colleagues in gastroenterology, head and neck surgery, orthopaedic surgery and urology (Figs. 5 and 6).[12] Rather primitive but promising early experience led to collaborations with various endoscopy manufacturers including Karl Storz (Culver City, CA, USA), Olympus (Lake Success, NY, USA), Baxter-Edwards (Irvine, CA, USA), Microvasive (Milford, MASS, USA) and Nobles-Lai (Santa Ana, CA, USA). Collectively, they provided us with over US$ 150,000 of standard and custom-made equipment. In return, we evaluated the products and helped to develop their product lines.

From August 1986 to December 1988, we conducted a prospective study of 60 consecutive vascular endoscopy cases in 52 patients.[13] This study indicated that angioscopy was useful in allowing direct visualisation of luminal topography and for documenting results for future reporting. However, there was no significant improvement in primary or secondary patency or limb salvage. Furthermore, the angioscopic findings led to a 40% incidence of additional intervention without any improvement in early or late results, leading to a suspicion of over-treatment. This view was further supported by the fact that 19 patients who underwent thrombectomy with angioscopic visualisation had a worse primary and secondary patency than comparable age-matched controls who underwent thrombectomy without angioscopy. Thus, we concluded that routine angioscopy as an adjunct to endovascular reconstructive procedures may not necessarily be of clinical benefit, although it might be an interesting teaching and research tool. Also, the angioscopic equipment was somewhat costly and difficult to set up and maintain.

Intravascular ultrasonography

In 1988, we began to evaluate intravascular ultrasonography. We were disappointed by the limited ability of angioscopy to provide information of the arterial wall and the degree of stenosis. Intertherapy Inc. (Costa Mesa, CA, USA) provided intravascular ultrasound equipment. In 1989, Boston Scientific/Medi-Tech (Watertown, MA, USA) also agreed to lend their intravascular ultrasound equipment, and preclinical safety and feasibility studies in live animals and human cadavers began. Then, between February 1990 and January 1991, intravascular ultrasonography was performed in eight patients undergoing nine lower extremity revascularisation procedures.[14] The ultrasound equipment correctly identified dissec-

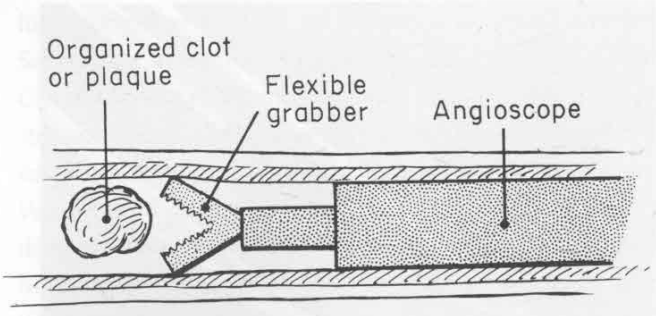

Figure 5. The authors' conception of a flexible grabbing catheter inserted through a vascular endoscope to retrieve a piece of organised clot or plaque particle.

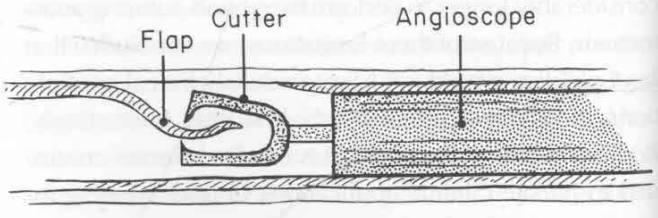

Figure 6. The authors' conception of a flexible cutter with sharp, "piranha-like" jaws passed through a vascular endoscope to cut an intimal flap.

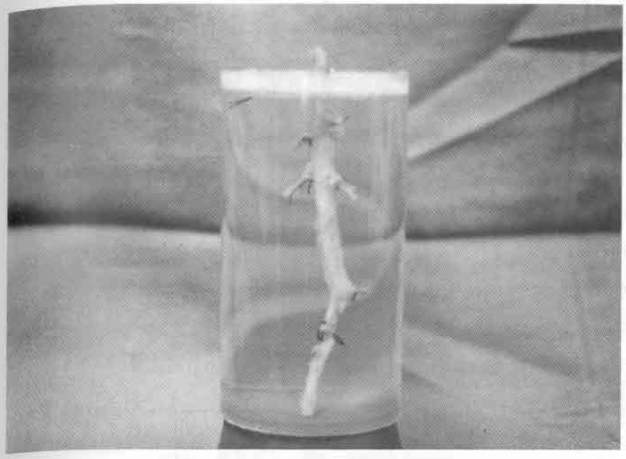

Figure 7. Transparent gelatin arterial support model.

tions, intimal flaps, residual stenosis and thrombus following endovascular procedures. However, the equipment was cumbersome to use and required a long initial set-up time. We found that conventional angiography and angioscopy together detected similar abnormalities.

Models for Endovascular Device Evaluation

During these early years, we evaluated numerous new devices. Prior to using any equipment in humans, we tested it in live animals, whole cadavers, or harvested human cadaver arteries. This taught us how to use the equipment safely and properly in order to achieve optimal results. However, the use of animals for this purpose was expensive, perhaps wasteful, and certainly generated protest from community animal rights activists. In addition, many therapeutic devices needed testing in abnormal human cadaver arteries, and these were not always readily available since our Willed Body Office could not always provide us with fresh cadavers. Accordingly, we sought various alternative models for endovascular device evaluation and devised three different models.

Gelatin arterial support model

A reliable model that would support harvested human cadaver arteries was needed. We felt that this should be easy to set up and readily available, simulate the *in vivo* soft tissue support of the artery, and allow visualisation of the artery during testing procedures. We devised a clear gelatin mould model in which freshly-harvested human cadaver arteries were embedded (Fig. 7).[15] A gelatin concentration of 130 g/l plus 1% agar provided surrounding arterial support simulating the mechanical properties of muscle. Furthermore, gelatin was transparent and allowed adequate visualisation of the embedded artery. This model proved to be highly successful and allowed evaluation of mechanical atherectomy, laser thermal-assisted balloon angioplasty, angioscopy and ultrasonography in over 100 *ex vivo* experiments.

Arterial preservation

However, we were limited by the availability of fresh human cadaver arteries as human cadaver availability was unpredictable and limited. An obvious solution was to harvest all arteries when an appropriate human cadaver became available and then preserve these arteries for future use. A literature review to determine the optimal arterial preservation methods found no satisfactory reports to suit our needs. Accordingly, a series of experiments to determine optimal preservation techniques was conducted. Human cadaver arteries immersed in Bacitracin/Polymyxin/Amphotericin with 0.9% saline solution and stored at -20°C or -80°C were adequately preserved for at least three months.[16] This technique proved to be highly successful and provided an abundant supply of intact preserved human cadaver arteries for device evaluation.

UCLA endovascular training model

As vascular surgeons around the country became more interested in endovascular surgery, we saw a need to develop a model to train our colleagues in the various endovascular procedures. With Pacific Research Laboratories, Vashon Island, Washington, a small company that made plastic training models for orthopaedic surgeons, we designed a life-sized endovascular surgery training model which was later copyrighted. This model provided an arterial system that simulated arterial blood flow, allowed quick insertion of harvested human cadaver arteries as interposition grafts at strategic anatomical sites, and was transparent so that the entire procedure could be visualised from the outside (Figs. 8 and 9).[17] The life-sized dimensions and life-like aspects of the model allowed an investigator or student to perform percutaneous or open procedures in a very realistic fashion. Later, artificial arteries were designed to accompany this training model

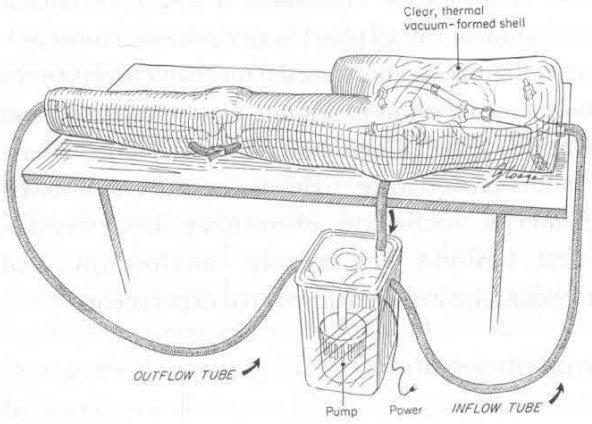

Figure 8. Illustration of the authors' transparent endovascular training model.

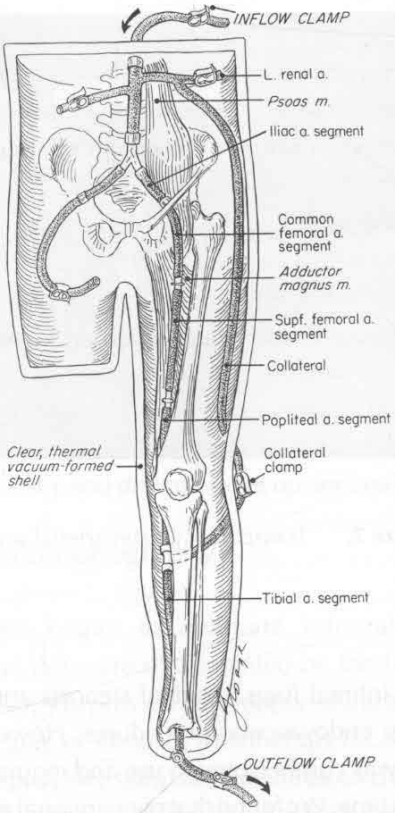

Figure 9. The endovascular training model extending from the xyphoid process to the left ankle. The vascular system is encased in a clear, thermal, vacuum-formed shell in the shape of the human body.

and these replaced the human cadaver arteries which were now becoming harder to obtain. These artificial arteries contained plaque-like material made of chalk, bees' wax and agar in a combination that provided a similar melting point to that of calcified human atherosclerotic plaque. Thus, these artificial arteries allowed the investigator to practise laser-assisted balloon angioplasty and atherectomy.

Endovascular Educational Programme

Perhaps the most significant and lasting contribution that we have made to endovascular surgery is the organisation of educational programmes and materials. Shortly after the formation of the UCLA Laser Committee in January 1986, we organised an education subcommittee to develop laser courses comprised of lectures and practical, hands-on experience. Initially, courses were for UCLA faculty and residents. The first laser course was held in May 1986, with an overwhelming response. A total of 55 faculty and residents participated in this course, numerous laser companies provided equipment, and laser experts from various parts of the country came to offer their teaching services. Over the next two years, several laser workshops and courses were conducted for various subspecialties including ophthalmology, general surgery, gastrointestinal surgery, neurology, pulmonary medicine, dermatology and gynaecology.

As we gained experience with angioscopy, we saw the potential for broader applications. However, there was still a significant learning curve in setting up and organising angioscopy equipment. Several angioscopy equipment companies asked us to organise a nationwide angioscopy course at UCLA to teach other vascular surgeons about its potential clinical applications, techniques, procedures, and advantages and disadvantages. With the generous sponsorship of these companies, the first angioscopy course was held in April 1988. Over 150 surgeons attended this first course, which consisted of lectures and hands-on experience in the animal laboratory.

During the latter part of 1987, mechanical atherectomy, laser-assisted balloon angioplasty, and angioscopy and intravascular ultrasonography began receiving much attention in the vascular community. It became evident that a new field within vascular surgery was emerging. This new field was termed "Endovascular Surgery" to describe surgical procedures performed endovascularly via a remote site. This new term was first

used publicly during a discussion of a paper presented by Matthew Selman at the Third Annual Meeting of the Western Vascular Society in Monterey, California. We ended our critique of Dr Selman's paper with the following editorial comment:

"I am not suggesting that we all jump on the atherectomy/angioplasty bandwagon at this time. What I am suggesting is that we surgeons critically and actively participate in the investigation and development of this emerging field of what I call "Endovascular Surgery". And surgery it is. These procedures are invasive, require special technical skills, involve cutters and abraiders of sorts, involve careful pre-operative evaluation, conscientious postoperative care, and long-term follow-up. They also involve a thorough understanding of the anatomy and pathophysiology of the disease and a thorough understanding of the instruments. No one should be better qualified to perform endovascular surgery than the vascular surgeon. We as vascular surgeons must stay at the forefront of this new technology. Only in this manner can we step into our proper role, if and when any of these devices are shown to provide significant patient benefit."

In May 1989, we conducted our first annual UCLA course on Endovascular Surgery, which covered the entire spectrum of this emerging field. We invited an internationally recognised faculty from various subspecialties including surgery, cardiology, radiology, engineering, physics and industry, all of whom had contributed to the multidisciplinary field of endovascular surgery. This course included lectures and laboratory sessions using the endovascular surgery training models described previously. Over 300 participants enrolled in this course and at least 100 other faculty members and industry sponsors participated.

In the initial planning stages of the course, we decided to put together a book to accompany the course. We asked each of the participating faculty members to contribute a chapter. This book, the first in the new field, was released at the First Annual UCLA Program on Endovascular Surgery in 1989.[18]

Epilogue

Unfortunately, our initial optimism and euphoria following the first UCLA Endovascular Program quickly gave way to more sombre, realistic expectations over the next year. Our earlier failures of atherectomy, laser-assisted balloon angioplasty and even angioscopy had predicted a major down-swing of the pendulum in endovascular surgery. Other investigators were beginning to confirm the negative results. Laser angioplasty in particular was getting a bad name, as major failures and complications were being reported. It was also clear that many physicians were abusing and overusing this new technology. We discovered that some participants of our Endovascular Surgery Course had taken the Continuing Medical Education certificate to their hospitals to obtain permission to perform endovascular procedures at their institutions without any proctoring or Human Subjects' Protection Committee approvals. Accordingly, we terminated our Endovascular Surgery Course after May 1990. We also began revising our textbook to give a more critical view of the endovascular field. The second edition was published in 1992, and included numerous warnings about the negative results and a plea for a more controlled development of this field.[19]

In reviewing the literature, it was clear that many of the earlier reports were misleading due to improper reporting. It was virtually impossible to compare results from different institutions and different techniques because of the widely disparate reporting methods. Consequently, we collaborated with Robert Rutherford and the Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) to organise an *ad hoc* subcommittee to provide standardised guidelines for reporting endovascular results. This led to the publication of the "Reporting Standards on Endovascular Procedures" which is now widely followed.[20]

Future Developments

Because of the poor late results of balloon angioplasty, atherectomy and laser-assisted balloon angioplasty, our efforts since 1991 have been directed at addressing the restenosis problem, in particular, intimal hyperplasia. Darwin Eton, our first endovascular fellow, studied the potential use of photodynamic therapy to prevent intimal hyperplasia;[21] Hugh Gelabert, a colleague in our vascular section, is currently studying the effects of smoking on hyperplasia; other research residents including Arun Chervu,[22] Michael Colburn[21,23,24] and Michael Law[24] have evaluated the use of angiotensin-converting enzyme inhibitors and steroids to prevent intimal hyperplasia.

From a technical point of view, we have ventured into various areas: endovascular valve lysis and side-branch obliteration during *in situ* saphenous vein bypass,[25]

endovascular grafting for abdominal aortic aneurysms,[26] endovascular grafting for arterial occlusive disease,[27] ultrasound-guided balloon angioplasty, thoracoscopic cervicodorsal sympathectomy,[28] and laparoscopic surgery for aorto-iliac disease.[29] All these techniques are still in the investigative stages. Some preliminary results are quite promising but, based on our previous experience, we advocate caution in interpreting the results and strict adherence to rigorous scientific methods of investigation. The true value of these new techniques will not be known for at least another three to five years. In the meantime, we encourage vascular surgeons to stay at the forefront of this emerging field of Endovascular Surgery.

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