Developing and financing new technology

W. Randolph Chitwood, Jr, MD

Dr Chitwood

Cardiothoracic surgeons must become more involved in developing new technology to improve patient care and further the specialty. Surgeons encounter unique observational experiences in the operating room, which can provide a wellspring of innovative ideas. However, to achieve true value of a clinical benefit, unique ideas must be expanded, modeled, developed, and applied. Collaboration and a new way of thinking for cardiothoracic surgeons must emerge to be effective in this arena. With retrenchment of clinical revenues, project funding has focused increasingly on industry, government, and private channels. Herein, both developmental pathways and methods of funding new technologic ideas are examined.

In questions of science . . . The authority of a thousand is not worth that humble reasoning of a single individual.

—Galileo Galilei

Keeping Cardiothoracic Surgeons in the Game

Surgeons are experiencing increased challenges to improve patient care and service efficiency with fewer complications in older patients with more complex conditions. At the same time, oversight and “score card” reporting have broadened expectations toward less surgical invasiveness, better cost containment, improved patient quality of life, workforce optimization, increased patient comfort, fewer readmissions, and more outpatient care. Concomitantly, patients have become cognizant that catheter-based procedures are much less invasive than conventional surgery and that results are improving rapidly. Our cardiology colleagues have fostered an explosive growth in new techniques and devices for treating coronary artery disease, congenital heart defects, peripheral vascular disease, and complex arrhythmias. Vascular surgeons and cardiologists have developed effective stents for aorto-iliac, carotid, and renal arterial lesions. In many centers aortic aneurysms are treated routinely with percutaneous endovascular grafting. Recently, Osterle¹ predicted that in 10 years patients undergoing an interventional procedure in “U.S. catheterization laboratories” would jump from 800,000 to over 10 million yearly. Despite these advancing nonsurgical therapies, many opportunities still exist for cardiothoracic surgeons.

To expand our specialty and in many instances *remain in the game*, cardiothoracic surgeons must develop imaginative technology that expands and extends our capabilities toward completely new horizons. We must become involved in the development and application of catheter-based therapy. A new breed of surgeon must evolve to one comfortable with both catheter-based therapy and open procedures. Over the next 50 years, the expansion of gene-based treatment for cardiovascular diseases seems nearly limitless, and surgeons must become integrated into this evolution. Similarly, we must develop, improve, master, and teach truly less invasive surgery through telesurgery using micromanipulation devices. To achieve these goals, established cardiothoracic surgeons must encourage and support new idea development. Moreover, we must teach younger investigators how to protect, develop, and fund their ideas. Osterle closed his article by saying, “The next generation of cardiologists and heart surgeons will likely share similar training experiences . . . a new endovascular-cardiovascular specialist will likely emerge in the process.”¹ Our specialty must meet this challenge through innovation, imagination, and integration.

From the Department of Surgery, Center for Minimally Invasive and Robotic Surgery, Brody School of Medicine, East Carolina University, Greenville, NC.

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Address for reprints: W. Randolph Chitwood, Jr, MD, Professor and Chairman, Department of Surgery, Brody School of Medicine, East Carolina University, 600 Moye Blvd, Greenville, NC 27858-4354 (E-mail: chitwoodw@mail.ecu.edu).

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TABLE 1. Seven da Vinci principles: A guide for innovation

<i>Curiosità</i>	Insatiable curiosity and quest for continuous learning.
<i>Dimostrazione</i>	Commitment to test knowledge through experience and to learn from mistakes.
<i>Sensazione</i>	The continual refinement of the senses, especially sight, as a means to improve experience.
<i>Incertezza or Sufmato</i>	Willingness to face and understand ambiguity, paradox, and uncertainty.
<i>Arte/Scienza</i>	A balance between art, science, logic, and imagination.
<i>Corporalità</i>	Cultivation of grace, ambidexterity, fitness, and poise.
<i>Connessione</i>	A recognition of the interconnections of all things and phenomena.

The Innovation Imperative

Recently, Toby Cosgrove,² in his 1999 Presidential address to The American Association for Thoracic Surgery (AATS), chided cardiothoracic surgeons to, “think anew and act anew in clinical practice, education, research, and health care delivery.” He stressed that, “At no time in human history has the potential been greater for translating biologic knowledge and technical capability into powerful tools for preventing and treating disease.” He was speaking of *translational research* in which biologic concepts are expanded to clinical applications through planned development and clinical trials. *Innovation* is defined as the alteration of what is established with the introduction of new elements to develop a novel practice method. It requires an entirely new way of thinking about old problems, as well as discovering new ones to solve.³ Innovation has been a touchstone for progress in medicine and science over the centuries. Innovative thinking is the first step to development of new ideas in practice and technology. Surgeons must do more than just “dust off” and reapply the term to current methods. We are in another age of surgical discovery, similar to that of John Hunter and Alfred Blalock, but one in which technologic complexity has increased logarithmically in a shorter time period. Advances in computer, electronic, engineering, and information technology have catapulted ideas, impossible to develop formerly, into routine clinical application.

In the late 15th century, Leonardo da Vinci cultivated personal qualities that sculpted his ingenuity and became the impetus for his inventions, discoveries, and art (Table 1).⁴ His quest for learning, willingness to embrace ambiguity, benefiting from mistakes, and for experimentation are familiar to every surgeon. These ideals, added to his pursuit of a balance between logic and imagination as well as sensory refinement, cultivation of ambidexterity, and an

understanding of biosystem interconnectivity, became the wellspring of Leonardesque innovation. Many of these are inherent in our surgical training programs and daily lives. Ideas for developing new surgical technology may be spawned in operating rooms, at the bedside, or even in odd places, such as hardware or cooking stores. Although sparks for imaginative ideas may emanate from simple observations, they must be cultivated to reach even potential value. Cardiothoracic surgeons have always been creative, and technology development seems natural.

Technology Evolution: Timing Is Important

In the past, cardiothoracic surgeons have been forward-thinking innovators. The individual contributions of Nina Braunwald (valves and biosurfaces), Alain Carpentier (bio-prosthetic heart valves), Denton Cooley (new operations), John Gibbon (cardiopulmonary perfusion), Michael DeBakey (vascular grafts), C. Walton Lillehei (congenital heart surgery), Norman Shumway (transplantation), Albert Starr (mechanical heart valves), and Magdi Yacoub (surgical immunology) typify this innovative spirit. However, for their innovations to become a true advance in surgery, their ideas had to be co-mingled with other contemporary technologic advances in other disciplines.

It is just as interesting to review *failed* early attempts to develop complex surgical technology. Many of the problems in past eras had potential solutions, but other factors prohibited development. In 1900, Payr^{5,6} published very good ideas regarding blood vessel connectors. His magnesium rings were innovative and unique, providing everted endothelial apposition and a stented opening. Why did this device not develop? Recently, proximal aorto-graft connectors have become very successful. Why have these worked and why will graft-coronary anastomotic devices succeed? Modern engineering concepts and new materials now enable avant garde developmental potential. New deformable hybrid metals have geometric memory, which can affect efficient, accurate deployment. Moreover, interactions between coagulation systems and conduit materials have been defined better, and pharmacologic agents can inhibit interfering coagulation cascades. Thus, Payr’s idea, which from the start manifested great latent potential, waited 100 years to become a practical development.

Similarly, Cutler and Beck⁷ fabricated a cardioscope with the notion of examining and treating cardiac valvular stenosis in beating hearts. Also, Sakakibara and associates,^{8,9} using an improved cardioscope, closed an atrial septal defect and performed aortic valve commissurotomies. These attempts never advanced to the next level because of blood opacity, inferior optics, and light transmission impediments. Today, we can stop the heart, look inside with 3-dimensional high-resolution cameras, and repair valves.^{10,11} Moreover, echocardiographic techniques now allow us experimentally to visualize and repair valves in

TABLE 2. New technology development: The matrix for success

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- A clinical goal paramount
 - Benefits and safety for patients paramount
 - Scientific curiosity is key
 - A historical subject review
 - Develop an organized approach
 - Prioritize and apply new concepts
 - Re-engineer and re-apply
 - Collaborate with different disciplines
 - Learn new skills beyond training
 - Collaborate with industry
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beating hearts. Cutler, Beck, and Sakakibara's concepts were well conceived but remained undeveloped because of inadequate coopting technologies. As evidenced by the space program, technologic advances in one field may beget diverse developments in others. New ideas must be evaluated in the context of other contemporary advances; they can ripen more effectively by "pinging" against other innovations. For surgical scientists today, many more support options are available than in past eras, and these have resulted in what really is a technology development "amplification factor" not seen previously.

Developing New Technology: The Matrix for Success

The route to successful development of new technology is paved with a heterogeneous matrix (Table 2), characterized by many Leonardesque principles described earlier. Clearly, there must be a clinical goal, and the development process must be focused on this ultimate application. Re-engineering and/or redesign of an older idea, product, or application may abbreviate the time to project success. Ideas can be triggered in either a creative or mundane environment, but they must be developed. The idea then must be "sold" conceptually to someone who can help improve it, provide funding for expansion, or who wants to own the idea. Whatever the path, the ensuing steps are to re-engineer and smooth the developing idea. This all has to be done before the first attempts at clinical application are possible. Generally, a process similar to the one shown in Table 3 is required to bring an idea to either clinical trials or full application.

Surgeons should not hesitate to learn entirely new skills and collaborate with diverse disciplines. During recent advances in catheter-stent technology, cardiologists gained a great deal of experience by working with bioengineers and cellular scientists. Most of us do not have the resources to recruit experts in each area to our laboratories and must rely heavily on interdisciplinary and industrial collaboration. Many companies employ focused project scientists and engineers with whom surgeons can work closely. Project success can be enhanced through greater synergy between

TABLE 3. Idea to clinical application: The 10-point process

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1. Idea
 2. Intellectual property protection
 3. Financing
 4. Research
 5. Laboratory and clinical trials
 6. Peer journal publication
 7. Design and redesign
 8. Product development
 9. Education and training
 10. Clinical application
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diverse scientific interests and talents. For example, robotics and angiogenesis seemingly have dissimilar applications; however, robotic systems could become the springboard to efficacious gene therapy by providing a facile epicardial delivery system for angiogenic agents.

Translational research bridges the gap between basic science studies and clinical applications. This is the area of research that seemingly will become the most fruitful for surgeons. Pre-clinical trials may include simulated human environments, animal studies, cadavers, or ethical studies in informed patients. Development activities are then focused on application of these research and engineering techniques to solve problems resulting in new devices, systems, materials, or procedures. Design relates to developing product testing protocols, as well as models or prototype construction. Here, structural or process plans are developed, conducted, and finalized by using either computational engineering design capabilities or biologic modeling. Finally, after the piece of new technology has been modeled, educational support must be developed to train surgeons, ancillary health practitioners, and research coordinators. Simultaneously, public education should be fostered to provide better understanding of future product or device application. Ideas must be expanded to this point before serious clinical trials can begin evaluation. The Food and Drug Administration (FDA) has specific standards regarding new device/drug/product safety, efficacy, informed patient consent, and education of clinical trial participants. Our institution has developed a robotic training center and curriculum designed to provide didactic and technical experience for surgeons and their operative teams who wish to begin robotic clinical trials.¹²

Technology Development Opportunities for Cardiothoracic Surgeons

Today, more than ever, we have opportunities to sculpt our technologic future in cardiothoracic surgery. Some ideas are simple to develop, and others are difficult. Instrument design and modifications are usually the first innovation leap for surgeons. Surgeons have the benefit of seeing first-hand clinical applications that warrant development of new devices and instruments. Many companies are pleased to work

TABLE 4. Opportunities for new technology: Discovery and innovation

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- Anastomotic devices
 - Atrial arrhythmia therapy
 - Biocompatible materials
 - Bioadhesives
 - Cellular biology
 - Myocardial cellular restoration
 - Neo-endothelialization
 - Angiogenesis
 - Cellular redifferentiation
 - Natural vascular conduit modification
 - Inflammatory response modification
 - Heart failure
 - Ventricular remodeling
 - Geometry altering devices
 - Mechanical support devices
 - Heart valves
 - Interventional catheter technology
 - Thoracic aortic stent grafts
 - Treatment of aortic dissections
 - Perfusion technology
 - Radiosurgery
 - Tumor radiofrequency ablation
 - Robot-focused tumor ablation
 - Surgical robotics
 - Operative simulation
 - Navigation and positioning devices
 - Forced feedback
 - Surgical optics and vision
 - Tissue fixation devices
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with surgeons to perfect, re-engineer, or develop a new instrument. For example, the Scanlan and Pilling families have worked for years with surgeons to design, model, and improve cardiovascular instrumentation. For the surgeon, instrument design and clinical application are enjoyable and intellectually rewarding. Moreover, these contributions are well within the reach and time commitment of most surgeons. Intermediate areas of developmental difficulty include off-pump coronary surgery, surgical robotics, and videoscopic cardiac surgery. Areas that require the most expertise and collaboration are typified by fetal surgery, blood conduit development, cellular restoration, valve tissue engineering, and cardiac replacement pumps. Creation of new surgical imaging techniques requires many more resources, which become impossible without major industrial collaboration. Table 4 lists some of the current opportunities for academic and private cardiothoracic surgeons to develop new technology. Securing appropriate collaborators early in a zealous project is central to ultimate success.

Entrepreneurialism and Industrial Partnerships

For cardiac surgeons the term *entrepreneurialism* was darkened temporarily because of the unbridled self-interest of a few. Several business co-ventures ultimately became political and ethical burdens to our specialty. This happened

when surgeons became involved in global marketing and company finance well before clinical efficacy and risks were established firmly. Device- and technique-related complications were minimized. At the same time, public advertising on television, by hospitals, in airline clips, and in magazines pushed this technology as a public consumer product. For a while, a patient's cardiac operation seemingly was not as good as a neighbor's unless specific commercial products were used. Surgeons who denied complications, boasted of unrealistic benefits, and invested in the financial success of the company lost a great deal of peer credibility.

Despite these lessons, business integration with academic investigation can be done appropriately and can provide economic stimulation for the development of laboratories, centers, and departments, as well as hospitals and universities. Many institutions have adopted "win-win" philosophies and encourage entrepreneurialism with returns through patents, royalties, and company equity. Tripartite business alliances are being encouraged between institutions, investigators, and industry. Surgeon investigators must be aware of institutional policies, their intellectual property rights, and ethical borders in these areas. Early co-venturing during development is appropriate; however, efficacy and safety should be established firmly before advanced clinical trials are begun. I think it prudent to have no financial interest in devices and applications in which the investigator is involved clinically. Although this opinion is not shared uniformly, it is the safest way to avoid public scrutiny and maintain maximal objectivity. Challenges in obtaining funding for new ideas have required many projects to be supported by prior business successes. Universities and clinicians have become more reliant on each other to provide a feedback mechanism to stimulate growth in their "technology think-tanks." Societal and institutional returns are obvious—improved health care, positive public relations, a premium faculty, and greater research funding.

Intellectual Property: Protecting Bright Ideas

It is imperative to protect *intellectual property* (IP) early in the development process. One should document discoveries, innovations, and ideas in a laboratory notebook with appropriate drawings. Entries must be signed by the investigator and witnessed by another person. The notebook should be kept in a safe place and entries should be copied periodically and mailed back to the investigator, postmarked and unopened for safe filing. Surgeons must understand their IP position before disclosures are made to industrial suitors or collaborators. In some instances institutional and university officers direct all IP activities. In this scenario the investigator must discuss ideas with university officials first and get permission to broker the idea. In other institutions the innovator may act as his or her own agent and interface independently with third parties developing the idea before returning to the university for permission. Most universities

specify that a portion of the rewards be returned to the school. The portion returned to the department, laboratory, or individual should be negotiated and approved by university technology transfer officers. Successful brokering can provide optimal return funding needed to expand idea development and design. One should negotiate with the department or university officials in advance of complete disclosure. Moreover, it is beneficial to renegotiate agreements when they remain too restrictive or provide too little incentive. Individuals should read all institutional employment and confidentiality agreements in detail. No matter what, it is important to review all university IP policies and agreements and then discuss them with technology transfer officers, university attorneys, and the departmental chairperson. It is key to determine exactly who owns your IP before discussing your ideas with anyone, no matter how “hot” your ideas may seem. Casual public conversations can threaten the primacy of your idea, as can any mention in a publication. The best possible relationship with the institution should be sought and a spirit of full disclosure and cooperation should be adopted, but only after the IP is protected. For additional help, patent attorneys, technology specialists, and experienced surgeons can help clarify specific situations.

Final protection of an idea, invention, or innovation must be secured through the federal patent route. Clearly, investigators and institutions are in the strongest financial negotiating position if the idea is developed fully and patented. Most universities have excellent patent attorneys who are helpful in this area. More independent individuals may have opportunities to secure a private patent attorney in a specific field. A *Provisional Patent Application* is usually the first entry into the US Patent and Trademark Office (<http://www.uspto.gov/>). This application provides a first to file date, international protection, and 1 year to file a formal application. Moreover, it is inexpensive and relatively simple to file; however, the idea is disclosed immediately to the public. Investigators have but 1 year to file both a US and international patent application. After this, the basic idea is disclosed globally and no other IP protection exists. A *Non-provisional Patent Application* requires full disclosure of the idea or device, is protective internationally, and is much more expensive to develop. A “utility patent” protects the way an article is used and works and a “design patent” protects the way an article looks. Some inventions may require protection by both types of patents.

Valuation of IP

Who should negotiate the value of your IP and how is it determined? When agents are retained to negotiate and determine the value of technologic innovations, less work is required by the investigator and more experience is gained. However, the individual becomes more dependent on the agent’s judgment and abilities. The investigator is actually

in a better position to determine value of his or her idea, but negotiations will require much more personal effort. Experience in this area definitely places surgeon investigators in a stronger negotiating position.

IP values depend on several issues. A completely novel or new idea generally has more value than an improvement of an existing device, method, or process but involves more risk and investment by both the inventor and acquirer of the idea. In determining the value of an idea, medical device and equipment manufacturers must determine whether the innovation adds significant value to their existing product portfolio and long-term business strategy. New product improvements often require further financial commitments and technologic development, and manufacturers also will factor in the costs to market and launch a final product to determine the value of the new idea or improvement. Usually the product market already has been developed, and the manufacturer’s hope to expand this opportunity is its incentive to evaluate new ideas. Companies are willing to pay royalties but shy away from giving equity. Small companies or start-up ventures are more inclined to offer equity or stock option incentives. The surgeon innovator and/or institution must determine the parameters for brokering their idea to the greatest advantage. Greater individual diligence on understanding the potential value of the idea gains the inventor more respect from the company, speeds the evaluation process, and places the inventor in a stronger negotiating position. When a completely new idea is developed, IP value is difficult to establish because the market or clinical use is not yet fully developed. Novel ideas, however, add true value to health care. Improving neurologic safety in high-risk coronary patients using “no-clamp” proximal vein graft–aortic anastomotic devices or atheroemboli filtering cannulas exemplify the value gained.

Well-developed and well-protected ideas have the greatest IP value and financial return. For unique ideas, economic value can be difficult to determine because no comparative measures exist. Thus, investigators should seek the advice of experienced consultants, attorneys, and “good friends.” They can help determine the latent value of an untested product. If an idea can be developed into a company, much more value and potential revenue exist. In this instance the uniqueness precludes significant competition enhancing financial value. Many universities now champion the development of “spin-off companies” and invest in the further product development, gaining an equity position. Investigators and institutions often need to garner outside investors but must be aware of potential dilution of the equity position. Exit strategies and acquisitions by another company may be profitable, but generally original investigator control is relinquished. If the idea results in a product and not company development, a weaker IP position exists since there is a great deal of competition. In the situation de-

scribed, dilution by outside investors is less and exit strategies generally relate to royalties and license agreements. Here, there is a higher likelihood of achieving a continued income stream with less risk and loss of product development control.

Financing Technology Development

Technology development strategies today must include creative ways to finance expensive ventures. Clinical revenues in cardiovascular surgery have fallen so sharply that this source nearly has become irrelevant for research and development. Also, traditional extramural granting agencies often are not willing to finance development of new clinical devices. The National Institutes of Health (NIH) and the American Heart Association (AHA), formerly major sources of funding for young and established cardiovascular surgical investigators alike, have directed many of their priorities toward nonsurgical areas. Conversely, industry support has become an important new resource, helping many worthy projects through engineering, patent application, capital, and clinical study support. Clearly, recent progress with vascular anastomotic devices, surgical robots, cardiac remodeling techniques, tiny cardiac assist pumps, endovascular grafts, bioadhesives, and off-pump instrumentation have evolved from creative partnerships between academic institutions, industry, and surgeons.

Today, more than ever, to fund development of new ideas and technology, investigators cannot rely on single sponsorship and must adopt a diversified strategy with multiple sources. My institution has relied on a combination of financial resources to develop our surgical robotics program. Diversification of a support profile for a laboratory or investigator has many positives and some disadvantages. The following financial sources are most commonly sought today for medical device and pharmacologic technology development.

University and institutional resources are less plentiful than in past years because of state and federal budget cuts, shrinking clinical reserves, increased expenses, and stifled philanthropy. Most medical school deans and departmental chairs enthusiastically support translational research and technologic innovation; however, their financial resources have dwindled because of falling clinical income and indirect-cost rebate reductions by university systems. However, in some institutions venture capital arms have been created specifically to fund health care-related technology. Moreover, university foundations, established through fund raising campaigns and planned philanthropy, may be sources for "starter" grants for good ideas, especially for young investigators. Most university coffers are not prepared to fund technology development in perpetuity and other sources must be engaged.

Philanthropy may be directed to purchase capital equipment, as well as provide naming opportunities of facilities

and laboratories. A cardiothoracic surgeon's community and university contacts may provide ideal opportunities for financing idea development. As most extramural granting agencies generally prefer not to provide funds for equipment and facilities, direct philanthropy from grateful patients or industry is an important source for necessities required to begin clinical and basic science research. Good friends of the institution are becoming more helpful in this area, and university contacts should try to minimize restrictions on these funds and broaden this venue for financing new research and development.

Charitable trusts and private foundations often have a scientific arm that is interested in health-related research. Direct contact with these groups can be made by investigators or through institutional avenues. Available funds are usually moderate in size and provide 1 to 3 years of support. These resources are usually directed toward experimental design and development rather than for significant salary, capital, or facility support. Working with these groups is particularly satisfying and many important contacts can be established.

Extramural granting agencies such as the NIH and AHA remain sources for funding focused projects and in some instances fellowships for junior faculty and postdoctoral candidates. The new National Institute for Biomedical Imaging and Bioengineering (<http://www.nibib.nih.gov/>) supports basic and applied research in biomedical imaging and bioengineering for good ideas, design, development, translation, and application of new medical technology. This agency is interested in funding multidisciplinary, collaborative biomedical research efforts with a translational motive. Interested investigators should contact directors of these programs for guidance. Requests for proposals (RFP) are published on the above NIH Web site and should be reviewed periodically.

Surgical specialty foundations are directed toward developing and funding young clinical and basic science investigators. These foundations have partnered with industry, philanthropists, and in some instances governmental agencies to fund and oversee peer-reviewed surgical research. The Thoracic Surgery Foundation for Research and Education (TSFRE) has been instrumental in funding young academic cardiothoracic surgeons, as well as residents. The TSFRE and the National Heart, Lung, and Blood Institute recently have jointly sponsored the Mentored Clinical Scientist Development Award Program (MCSDA), which promises to expand research abilities of young academic cardiothoracic surgeons (<http://www.tsfre.org/doc/5401>). This support extends for 5 years and is not renewable. The American College of Surgeons and American Surgical Associations also have time-limited grants for junior faculty and resident research development. The AATS sponsors the Robert E. Gross Research Scholarship (<http://www.aats.org/>

doc/4926). Each of the above is very helpful during residency training, in the initial phases of a laboratory start-up, or in an early surgical career. These are not designed to fund established surgical investigator projects but to “jump start” innovative young investigators. Specialty self-funding represents a major advance, which has been needed to develop young innovative surgeons, who are the key in directing our technologically driven future.

Angel investors may be interested in either co-funding or purchasing an idea after it is initially developed and protected. Angel investors are usually individuals who put part of their wealth in a specific project development. Investigators must be sure that they are working with qualified investors with a credible track record. Surgeons who work with angels should definitely seek the advice of attorneys or specialty consultants. These individuals can help with due diligence in determining the suitability of these investors.

Industry may want to buy either a developed idea or one in its infancy. Also, industry may invest in the development of the idea. Investment may be done to obtain a competitive advantage over another product or company. Also, it can be done to block competition and avoid brokering the idea to a competitive company. For the investigator these sources provide the least equity position of all partnerships; however, industry support may be a good financial route for idea development. The innovator may lose control of the direction of his or her idea after a company gains a large part of the development authority. In fact the company may table the idea and stop development just to prevent competition with a similar item already in their product line. In other words, loss of control can result before negotiations are complete without careful analysis and consultation.

Industry developers often look toward universities and surgical departments to provide laboratory venues for product development. Generally, these ideas have been protected, prototyped, and developed partially. Many private and university laboratories have advanced technologic capabilities and can facilitate long-term experimental modeling. Such facilities provide ideal venues for product development and maturation. Companies benefit from surgical expertise and the reduced costs incurred through “out-sourcing” of both facilities and technical personnel. Contractual agreements should be made between the institution and company before studies are begun. Institutions and laboratories can profit greatly from alliances with industry, and these resources can be used to fund other projects. Also, this venue provides greater opportunities to evaluate a specific technology. Similarly, to educate surgeons in clinical trials and some FDA approved technology, industry partners often provide institutional educational grants for training centers. Any training profits can be used to finance other laboratory and developmental projects; however, care must be taken when negotiating such agreements. Many compa-

nies will desire to restrict or control the use of competing products in training facilities they have funded or support. Institutions must weight these considerations against their goals to maintain clinical objectivity.

Venture capital funds have been an important financial source for development of new surgical technology. These large resources are composed of multiple investors who allow their agents to invest in projects that have a high probability of successful development with large potential economic returns. Individual investments are directed toward reaping a profit for the investors, and the only motivation is a return on investment. Thus, when an idea is dependent completely on venture capital for development, the investigator may easily lose direction to the dominant equity group. In this scenario there is loss of autonomy, and inventor/innovator longevity in the venture may be in jeopardy. Surgeon investigators must realize this risk. However, the potential returns to the institution or individual may be great if the idea moves to a competitive and/or marketable product with value and becomes a public company through an initial public offering (IPO) or is acquired by another company.

Clinical trials are rapidly becoming a major source of program funding. The Duke Clinical Research Institute (DCRI) typifies a well-organized effort directed toward major cardiovascular clinical trials (<http://www.dcri.duke.edu/>). Government agencies, pharmaceutical companies, health care institutions, or medical device companies may sponsor clinical trials. Companies are required to perform clinical trials, either to prove safety and efficacy or before full FDA approval. Sponsoring agencies have relied on academic investigators and institutions to design practical protocols, assure patient enrollment, train participating institutions, and perform sophisticated data analysis. Each of these co-ventures begins with a contractual agreement between the institution and sponsor. Institutional remuneration for these services maintains analysts, statisticians, nurse coordinators, and faculty salaries. When done well, clinical trials are co-beneficial to investigators, institutions, companies, and patients. Multiple clinical trials provide a pathway for institutional and technologic growth from patient recruitment, academic publications, and financial support. Moreover, public education elevates a center's stature locally and nationally. A great deal of information regarding current clinical trials may be obtained from the NIH (<http://clinicaltrials.gov/>).

Conclusion: Securing Our Technologic Future

Change is difficult for established surgeons, who rely on practices that have rendered constantly improving clinical results in the past. However, as Cosgrove alluded in his address, the developmental elastic modulus for many cardiac, vascular, and thoracic surgical procedures has been reached. Although room exists for improvement of tradi-

tional operations and devices, now is the time for us to spawn imaginative ideas, and develop specialty-based technology. This year the Society of Thoracic Surgeons (STS) and the AATS co-sponsored TECHCON 2002. This conference is the first in a series of society co-sponsored conferences designed to provide the most up-to-date information on technologic advances as they pertain to cardiothoracic surgery. Also, AATS/STS program committees have made special efforts to provide state of the art technology lectures and abstract presentations in their annual scientific programs. Ideally, these professional society efforts will become a growing "tsunami," expanding technologic innovation for our specialty. Nearly 100 years after the first air flight, the innovative spirit of the Wright brothers comes to mind. They did the impossible with the impossible. And it all became what is now possible. The "innovation imperative" is real, and cardiothoracic surgeons must become masters of this environment to continue to optimally care for our patients.

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