CLINICAL RESEARCH STUDIES

From the Midwestern Vascular Surgical Society

Presidential address: "Gentlemen, this is no humbug"—The role of natural selection in vascular surgery

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I want to thank the members of the Midwestern Vascular Surgical Society for giving me the opportunity to serve as the Society's 24th President. It has been my greatest professional honor, and I am deeply grateful for the friendship and collegiality I have enjoyed during my association with the Society.

As you know, our Society has been blessed with many leaders in vascular surgery, many of whom are here with us today. The previous presidential addresses have discussed all the major issues in vascular surgery, and many of these addresses were clearly ahead of their times. I was humbled and daunted by the task of addressing this learned group and afraid that all the good topics had already been taken.

OPTIMISM AND NEW TECHNOLOGY

Perhaps the only thing about which I am certain is that I have grown weary of the pessimism that seems to pervade vascular surgery lately. Although there is no shortage of gloomy topics to address, I would submit that there is still plenty in our specialty to inspire optimism. According to Webster's New World Dictionary, *optimism* may be defined as the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome. It does not necessarily mean things are good now, but it does carry the expectation that they will eventually be good.

Another of my great fortunes was to have done my surgical training at the Massachusetts General Hospital. On surviving the general surgical residency, I was given by my Chief, Dr W. Gerald Austen, a print of Robert C. Hinckley's famous rendition of the first public demonstration of ether anesthesia (Fig 1). Not too long ago, I was sitting at home staring at the picture, trying to come up with something reasonably worthwhile to say in this address. I then recalled the story of the occasion depicted here.[1] This incident took place in the original surgical pavilion on the top floor of Bullfinch Building in the Massachusetts General Hospital on October 16, 1846. The operating room was situated there to take advantage of natural lighting and is now called the "Ether Dome" in memory of that famous event. To set the stage, the surgeon was John C. Warren, one of the founders of the Massachusetts General Hospital and, arguably, one of the top surgeons in Boston at that time. The anesthetist was William T. G. Morton, a dentist who was an enthusiastic proponent of the analgesic qualities of ether, and the patient was Gilbert Abbott, who had a tumor of the neck that was to be removed by Dr Warren that day. It seems particularly appropriate for our specialty of vascular surgery that the tumor, it turned out, was a venous malformation. In contrast to the usual cries of pain associated with the surgical operations of that period, the patient, Mr Abbott, slept peacefully and, apparently, held reasonably still throughout the procedure, a remarkable accomplishment even today. Dr Warren was so impressed with this result that he turned to the gallery, in those days composed entirely of men, and spoke the legendary words "Gentlemen, this is no humbug." It occurred to me that these words, although spoken more than a century and a half ago, are just as applicable today when one considers some of the developments in vascular surgery.

Incidentally, I hope my lady vascular surgery colleagues do not find the quote offensive in its historic context, will understand my use of the quotation, and take no offense with Dr Warren or with me for the word "gentlemen."

I also hope you will not think me so arrogant as to equate myself with Dr Warren, but his statement to the gallery reminded me of my own reaction at the time I was first involved with early aortic stent graft procedures, usually performed on desperately ill patients. I suppose Dr Warren's statement could be reasonably broadened to in-

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Fig 1. "First Operation Under Ether" by Robert C. Hinckley (1853-1941) depicts the first public demonstration of ether anesthesia at Massachusetts General Hospital on October 16, 1846. (Reproduced with permission from Boston Medical Library in the Francis A. Countway Library of Medicine.)

clude, to some degree, each of the developing endovascular and minimally invasive techniques that are now available. Like all of us, I was taught the traditional, open techniques for vascular surgery and, over time, have become comfortable in their indications, reasonably proficient in their performance, and confident about the available options when things go awry, as they sometimes do. As a result, like many of us, I was initially skeptical regarding the indications for, or even the need for, some of these less invasive procedures. I was tempted to think, "If you are going to fix it, do it right the first time." We all know that our traditional methods for aneurysm repair, for example, are usually quite safe and durable. As evidence, consider these unpublished data derived from our departmental vascular registry. From 1989 through 2000, the hospital mortality rate for 1512 patients who underwent standard open repair of asymptomatic, infrarenal, abdominal aortic aneurysm was 1.7% for all age groups, and this figure has steadily declined from 9.6% three decades ago. Because our registry cannot distinguish between juxtarenal and infrarenal aneurysms, the recent figure is not strictly comparable, but the trend is clear. With consideration of yet our oldest patients, we found the 30-day hospital mortality rate for selected octogenarians to be less than 4%, and the operative survivors enjoyed comparable late survival rates to the general age-matched population.[2] So why do we even need stent grafts? All of us know that, although standard open AAA repair methods are very good, they do have substantial drawbacks, especially for the patient at high risk. Although we believe that we refuse to operate on very few patients who have aneurysms, all of us, especially those who practice at tertiary referral centers, have encountered some patients who are clearly at markedly increased, even prohibitive, risk for standard open aneurysm repair for a variety of reasons. It may be difficult to precisely define those factors that render some patients as prohibitive surgical risks, but, like the US Supreme Court's attempt to define pornography, most of us know them when we see them. In jest, one of my cardiac surgical colleagues once remarked to me that "Pretty soon we'll be digging people up to operate on them," and there have been times when I could easily believe he meant that statement literally. Furthermore, given our aging population and the observation that comorbidities tend to accumulate with age, it appears likely that we will encounter many more such patients who need aneurysm repair but are not expected to tolerate open repair well. It is often clear before surgery that, even if a patient at high risk were to survive open aneurysm repair, it is likely that enormous resources will be consumed during the long postoperative intensive care unit stay. Confronted with such a clinical dilemma, the vascular surgeon should be delighted to have all the therapeutic tools available that he can muster. Given all the exciting developments and changing technology in vascular surgery, why does there seem to be so much anxiety and pessimism among vascular surgeons? I think much of the problem involves the issue of control, and I would argue that the solution requires that vascular surgeons take control while maintaining a sense of optimism.

EVOLUTION AND VASCULAR SURGERY

I was also struck by the applicability to our specialty of an observation by Charles Darwin published only 13 years after the demonstration of ether anesthesia. The relationship between Darwinism and vascular surgery was explored extensively by Dr Frank J. Veith in his 1996 Presidential Address to the Society for Vascular Surgery and deserves reemphasis.[3] Darwin wrote, "I have called this principle, by

which each slight variation, if useful, is preserved, by the term Natural Selection."[4]

In his classic treatise, On the Origin of Species by Means of Natural Selection, Charles Darwin in 1859 described the inevitability of evolutionary change that appears to be inherent in the affairs of all living things, and it occurred to me that vascular surgery should be no exception to this general principle. I would submit that the developments in technology and social issues that some vascular surgeons find distressing are, in fact, nothing new and should be expected as part of the natural course of events. It seems ironic that if we really achieve our goal of continual refinement in prevention and therapy, we could ultimately bring about the extinction of our specialty. Fortunately, or unfortunately, depending on one's perspective, there are still ample inadequacies in the prevention and treatment of vascular disease to provide plenty of work for the foreseeable future. Vascular surgeons usually refer to these as interesting and challenging clinical problems. Consequently, if our fellows express concern about the future of open vascular surgery, I advise them not to throw away their scalpels yet. The potential, even fundamental, conflict of interest between progress and the maintenance of the status quo is best resolved with honest scientific investigation, with no strings attached, mediated by frank peer review. Those treatments with merit will stand the test of time, and there is plenty of opportunity for each of us to participate in the process of working out the details. The treatment of abdominal aortic aneurysm, for example, has evolved from early attempts at ligation and the induction of thrombosis to endoaneurysmorraphy and cellophane wrapping. Clinical investigation and peer review eventually lead to the recognition of the shortcomings of these methods, and they were eventually supplanted with graft replacement. The grafts themselves, and the techniques for implanting them, have also evolved. To me, endovascular grafting is just another refinement in the evolution of aneurysm management. Investigation and peer review in forums like The Midwestern Vascular Surgical Society will pragmatically determine its optimal application. It is clear to me that vascular surgeons are in the best position not only to perform but also to evaluate these procedures because they are the only group adequately equipped to handle any of the technical complications that may arise.

The factors that cause feelings of anxiety and pessimism among vascular surgeons seem to me to be principally social rather than technologic issues. Ideally, treatment decisions should not be motivated by a desire to maintain the status quo for socioeconomic reasons on one hand or to irresponsibly charge ahead in the name of progress in an attempt to corner market share for new technology on the other. Economic realities sometimes seem to blur these distinctions but should not overshadow the fundamental altruistic nature of medical practice and research. In an era of diminishing federal funds available for medical research, industry funding is increasingly necessary. However, investigators need to be open and honest in the disclosure of potential conflicts of interest and to refuse to permit financial concerns to influence the proper interpretation of data that might be unfavorable from an industry perspective. Practicing vascular surgeons need to make the effort to acquire adequate training in new technology, and our organizations need to help them in this effort. Scientific conferences, such as this meeting, provide the optimal arena to present, discuss, and challenge new ideas, and we should each make an effort to take part in some fashion.

Unfortunately, the evolutionary progress in vascular surgery that occurs with natural selection inevitably produces conflict and competition. One cannot help but be reminded of organisms competing for food and habitat. Those organisms that survive are the ones best able to adapt to the changing environment. Vascular surgeons, with their competitive nature and broad surgical training, are equipped to endure and are well motivated to adapt by acquiring the necessary skills to survive in the current environment.

CHALLENGE AND ADAPTATION IN VASCULAR SURGERY

The challenges to the specialty of vascular surgery are many but arguably can be grouped into three categories: those that involve technology issues, others that relate to social concerns, and still others that involve identity matters. These areas are clearly and inextricably interrelated, and the solutions to the problems they represent are complex and not always satisfying, much like an intricate multivariable equation with multiple sets of solutions. To survive the process of natural selection, however, vascular surgeons must prepare themselves, take full advantage of all their assets, and adapt to the environment.

From the technology perspective, I believe that we are in the third major wave of advancement in vascular surgery. The first was the development of open surgical techniques, the second was the refinement of the vascular laboratory, and now the third is the development of minimally invasive technology, which includes laparoscopic and endovascular techniques. We are learning that bigger may not necessarily be better in all circumstances. We have mastered the skills necessary for the first two waves of development, and I submit that we can handle those necessary for the third wave. I also believe that open surgical and minimally invasive techniques are complementary rather than exclusionary. We are finding that innovative combined approaches pioneered by members of our Society are also expanding the use of open and minimally invasive therapy.

Social issues include quality control and regulatory matters, such as certification and recertification of practitioners and vascular laboratories. Other issues involve financial and reimbursement issues that include fair coding practices to ensure just and adequate funding for patient care, education, and research and the opportunity to support our families and ourselves. The Lifeline Foundation deserves our support now, more than ever, in its efforts to supplement dwindling funds for vascular education and research. Malpractice and liability issues also fall into the

social area and are closely tied to public perception and expectations and patient satisfaction.

The identity category comprises those factors that mark vascular surgery as a distinct specialty and include the development of an independent board of vascular surgery. We, as a regional society, need to come to a consensus regarding our position on this matter. For the record, although I initially was skeptical, my own personal view is that now is a good time to push for an independent board of vascular surgery. We need a clearly defined identity. Vascular training issues undoubtedly need to be reassessed and are closely linked with our identity as a specialty. Although vascular surgeons, by virtue of our clinical skills and the breadth of our backgrounds, are in the optimal position to evaluate and use all the methods currently available for the treatment of vascular disease, we are seeing a decrease in the number of top quality candidates for advanced training in vascular surgery. I believe a significant contributing factor is the perception that our field and our identity are not defined well enough. We need to get the message out that our specialty is the only one in which the entire focus is the comprehensive treatment of peripheral vascular disease.

VASCULAR SURGERY, AVIATION, AND REALISM

All of these challenges offer opportunities. Those of you who know me well are aware that I most enjoy technology and working with my hands. You also know that it is unlikely that I would have the willpower to avoid bringing my long-standing passion for aviation into this talk. Since I began to fly light aircraft in early high school, before I thought about becoming a physician, I devoured information in this area and am now struck by some of the similarities between aviation and vascular surgery. Furthermore, I think it is fair to say that optimism is a good trait to possess if you fly airplanes. Although we would all probably agree that the commercial air carriers are not always the best role models for us with respect to service and public relations, I think there are some lessons we can learn from the strengths of the aviation community that are applicable to vascular surgery.

Aviation has many issues corresponding to those in vascular surgery, such as liability, competency assessment, training, and recertification and resource management involving both personnel and equipment.[5] However, I think the three areas that we arguably have most in common include the pursuit of complex technical activity, safety issues, and problems associated with public perception. Like vascular surgery, the aviation community is good at dealing with complex and rapidly advancing technology and has achieved a truly remarkable safety record. I believe that we can learn from these two areas of strength. Unfortunately, as with vascular surgery, the public's perception of aviation is not always optimal. Despite the remarkable performances in the field of aviation, the public often has unrealistic expectations regarding air safety and the ability to provide precise scheduling. Episodes of "air rage" are the result. We, as vascular surgeons, face the same public that routinely assumes there is virtually no risk involved with flying in a pressurized container 6 miles above the Earth's surface, at speed approaching that of sound and where the outside temperature is usually $-30°$ F to $-40°$ F in the summertime. We also face the same public that, for the most part, does not realize that the average level IV to V thunderstorm packs the energy of a small thermonuclear device, yet expects to arrive on time despite the vagaries of weather forecasting and the complexity of air traffic control in a crowded urban environment. The public also has become generally unwilling to accept risk, so it is easy to understand that the average patient, as well, expects an on-time, complication-free vascular operation as the norm, despite the comorbidities they have taken years to develop. Like the aviation business, we vascular surgeons are victims of our own success, and public expectations continue to sometimes exceed our consistent ability to deliver. The public takes for granted the remarkable results that they enjoy both from aviation and vascular surgery. I support the assertion that communication, especially public education, through initiatives like the joint societies' sponsored website, which will provide reliable and realistic information, is the best countermeasure to unrealistic expectations. The Midwestern Vascular Surgical Society is a participant in the developing national vascular website, and I would encourage you and your patients to use it. The URL is www.vascularweb.org, and it shortly will have links to our own Society's website and to the Journal of Vascular Surgery.

The aviation analogy leads to another important quality that vascular surgeons ought to possess, a sense of realism. *Realism* is defined as the tendency to face facts and to be practical rather than imaginative or visionary. Of course, a balance of realism and optimism usually works the best.

The National Transportation Safety Board conducts aircraft accident investigations to determine the probable causes and contributing factors that lead to the mishaps in a similar fashion to the mortality and morbidity conferences held by surgical departments. These thorough investigations are conducted for all airplane accidents, involving both commercial and general aviation aircraft. Recommendations for modifications of procedures and equipment then are made after a careful analysis of the findings. This process contributes to the enviable safety record for air travel in this country. Mortality and morbidity conferences should include all vascular interventions, not just traditional open procedures. It is unrealistic to think that the early devices for aortic stent graft placement, for example, are not going to experience materials failures and require periodic modification even after they are approved for general use. They clearly will need to become much more simple to use. Nevertheless, it is also unrealistic, and certainly not optimistic, to refuse to accept the idea that the current technology is only going to get better. To appreciate this, one needs only to reflect on the improvements in the field of anesthesia since Dr Warren's statement in 1846.

Good judgment is recognized as a major determinant of success in vascular surgery. It has also long been appre-

ciated that pilot error is a factor in more aviation accidents than is mechanical failure. Furthermore, rarely is a single large error responsible for an accident. Usually, the mishap is the result of a summation of a series of relatively minor errors or poor judgments. Contributing factors may include features inherent in the aircraft operating or air traffic control procedures that are not obvious but could easily be remedied if discovered. Recently, the publication of the Institute of Medicine Report has refocused public attention on the effect of human error on poor outcomes in medical treatment.[6] The true incidence rate of human error leading to adverse outcomes in vascular surgery is unknown with certainty, in part because the events are likely to be underreported because of fear of reprisal. This problem has been recognized by aviation authorities and was addressed by the establishment of the Aviation Safety Reporting System in 1975 with an agreement between the Federal Aviation Administration and the National Aeronautics and Space Administration. To lessen the probability of aviation accidents, this agency collects, analyzes, and responds to voluntarily submitted aviation safety incident reports. Pilots, or others involved in aviation operations, may submit a report if they are involved in an incident that they believe may have compromised safety. Important features of this system include confidentiality and the guarantee that reporters, subject to defined limitations, are granted immunity from enforcement actions for unintentional, noncriminal violations of statutes and regulations, which are reported within 10 days. It is also fundamentally different from a "whistle-blower" system because the only potential reward for the reporter is immunity from sanction. I would support the organization of a similar system for the reporting of medical safety issues or unintentional errors, an idea recently endorsed by Spencer.[7] Such a system should allow for the methodic analysis and reporting of safety issues in vascular surgery to minimize human error.

Those of you who fly know that one can never have enough fancy new navigation or communication instruments to cover all contingencies. The instruments Jimmy Doolittle used in 1929 during the first instrument flight are basically the same as those found in the panel of a typical modern single-engine airplane equipped for instrument flight. Although the fundamentals are exactly the same, the precision and reliability of modern electronic instruments are vastly improved. Nevertheless, the proficient pilot must still be prepared to fall back on the fundamentals in the event of an electrical failure. You also know that it is unlikely that any single device or refinement will eliminate the need for all the other tools we have available in vascular surgery. Consequently, it is important for vascular surgeons to not only acquire endovascular skills but to also maintain proficiency in standard open vascular procedures. We are now completing the first decade since Parodi, Palmaz, and Barone[8] published their initial experience with stent grafts for the treatment of abdominal aortic aneurysms. Aortic stent grafting is here to stay, and its use has been steadily increasing as illustrated by unpublished data from our own department. From 1996 through 2000, 40% of our infrarenal abdominal aortic aneurysm repairs used stent grafts. Furthermore, the rate of use is also increasing. For the year 2000 alone, 58% of all aortic aneurysm procedures in our department used stent grafts.

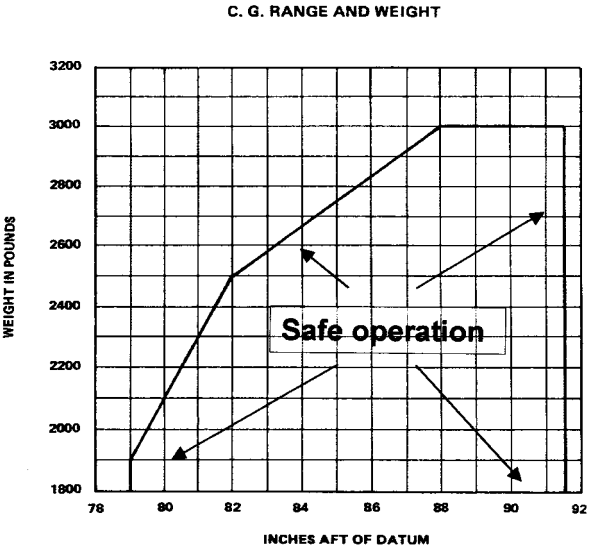

Fig 2. Graphic representation of weight and balance performance envelope of typical general aviation, single-engine, light aircraft. *CG,* Center of gravity.

Not all patients with aneurysms however, have anatomy that is optimal, or even suitable, for stent grafting with currently available technology. Frequently, open operations are needed to supplement endovascular procedures as attempts are made to broaden the applicability of these new devices. As you might imagine, there is an aviation analogy to this process. Aeronautical engineers often refer to the "envelope" when describing the graphs that depict the technical limits of aircraft performance. Exceeding the established performance limits invites what engineers euphemistically refer to as "catastrophic system failure." As an example, the weight and balance performance envelope for safe operation of my own small airplane is shown here, and, as for all certified aircraft, test pilots have verified it (Fig 2). At a particular gross weight, the aircraft center of gravity (CG) must be within the displayed performance envelope to maintain control. If the CG is too far forward, the pilot cannot exert enough backward force on the elevator control to pitch up the aircraft nose, and the aircraft becomes unmanageable. Conversely, if the CG is too aft at a given gross weight, the nose cannot be pitched down, and the aircraft again becomes uncontrollable. These limits can be roughly approximated with calculations during the aircraft design phase, but in practice, test pilots determine them before the aircraft goes into production. The test pilots repeatedly fly the aircraft with incremental changes in the weight and balance parameters until controllability limits are reached but hopefully not exceeded. This process is fondly referred to by test pilots as "pushing the envelope,"

and it takes little imagination to understand that it can be a harrowing experience. The average pilot needs to remember that if one chooses to operate his aircraft outside the verified performance envelope, one then becomes a test pilot and, therefore, must be willing to accept the risks associated with this activity. Successful test pilots are optimistic by nature but are not reckless. In fact, their sense of realism about the job usually makes them analytic and methodic. Analogously, if aortic stent grafting is used when the anatomy is not favorable, the vascular surgeon should expect that graft performance probably would not be optimal.[9] Of course, there are times when this concession might be desirable, but the decision to compromise should be an informed calculated one and, of course, the surgeon and patient should be prepared for the possibility of "catastrophic system failure." In any event, I believe that the currently available devices are, for practical purposes, still investigational in nature and, after implantation, must be followed closely for the development of endoleaks or migration, events that may require further treatment. I would agree with the assertion that endovascular repair, at this time, is best considered to be palliation rather than definitive repair of the aneurysm.[10] In my view, the patient should, at the minimum, understand these limitations and ideally be willing to participate in an appropriately approved experimental protocol. It is my own view that at the current time a good risk patient, especially one likely to survive a long time, is still optimally treated with a standard aneurysm repair. This is especially true if the geometry of the aneurysm is not optimal for stent grafting. Nevertheless, despite the recognition of potential durability limitations with the currently available devices, aortic stent grafting may still be the best choice for some patients in some circumstances.

NEW TECHNOLOGY AND RESPONSIBILITY

In addition to development of the technical skills for the tools we have at our disposal, I think we would agree that the freedom to use them also entails responsibility. We must acquire and develop four important assets: critical thinking, judgment, courage, and optimism. Critical thinking requires an open analytic mind and the discipline to pursue self education to make informed treatment decisions. New may be better but not always. But remember, the converse is also true. As others in our Society have eloquently stated, we need to continuously examine our own results and keep track of our patient outcomes to determine the optimal management for each clinical situation. Judgment is basically applied common sense on the basis of experience and current information. Courage is needed to take appropriate risks, especially in the face of incomplete information. Rational risk taking is indispensable for progress, but we should be willing to change the plan if circumstances require it. I believe optimism is essential. Given that change is inevitable whether we like it or not and given that technology will continue to improve and given that people will continue to need treatment for vascular disease for the foreseeable future, all of which are safe bets, I am optimistic that, in the long run, honest evaluations will sort out the relative merits and optimal indications for each of these new forms of therapy.

It is worthwhile for me to periodically review these ancient words taken from the Hippocratic oath as a reminder of where my primary focus should be when evaluating new technology. ". . . In whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrongdoing and harm, especially from abusing the bodies of man or woman, bond or free. . . ." (Hippocrates. The Physician's Oath. c. 460-377 BC).

At the risk of being considered naive, I think now is a great time to be optimistic. Each of our challenges represents an opportunity. We should embrace, not resist, the responsible development of new technology. Learn to use it; we need all the tools we can get. The trick is to develop the judgment and analytic thinking to know the limitations and the optimal indications for all the available means we have to treat vascular disease. Self education and experience are the means to acquire this. The environment is constantly changing and, like test pilots, we, as vascular surgeons and investigators, need to constantly be aware of the risks, benefits, and alternatives associated with our treatment methods. We should be thankful for the opportunities we have to learn to use these devices, to develop them, to sort out the indications, to treat the complications, to improve, to "push the envelope," and to evolve and adapt. We should also be thankful that we do not have time for boredom but that we do have the opportunity to have fun in this really exciting era in which we now find ourselves.

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