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Qian Peng
Editor-in-Chief



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A Tribute to Richard F. Edlich, MD, PhD

William C. Lineaweaver, MD
Editor-in-Chief, Annals of Plastic Surgery

Introduction

Richard F. Edlich was a Ford Foundation Scholar who gained early admission to Lafayette College at age 15. Three years later, he was accepted as an early admission student to New York University School of Medicine, where he received his medical degree. He completed a general surgery residency at the University of Minnesota Health Sciences Center under the guidance of his mentor, Dr. Owen H. Wangensteen, who is recognized as one of the twentieth century's greatest teachers of surgery.¹ During his eight-year surgical residency, Dr. Edlich also received his PhD. He completed his plastic surgery residency at the University of Virginia Health Science Center in 1973. He commenced his teaching career at the University of Virginia in 1973, beginning as Assistant Professor and eventually becoming Distinguished Professor of Plastic Surgery and Professor of Biomedical Engineering.

Multi-disciplinary Research Program

During his years at Virginia, Dr. Edlich founded, designed, and served as director of the 16-bed University of Virginia Burn and Wound Healing Center. Treatment of burn injuries and complex wounds at the center was a multidisciplinary research effort involving basic scientists as well as healthcare professionals. Dr. George T. Rodeheaver, the Edlich Research Professor of Plastic Surgery, is an organic chemist who played a leadership role in developing experimental models that effectively evaluated the merits of different wound healing products and techniques. Dr. John G. Thacker, Vice Chairman of the Department of Mechanical and Aerospace Engineering, developed reproducible performance tests that have been adopted by the medical industry as standards for surgical product testing.

Collaborative efforts resulted in numerous innovative products, surgical techniques, and tests used throughout the world. The Reinforced Steri-Strip™ (3M™, Minneapolis, MN) has been used in more than a billion patients for wound closure.² A surgical wound cleanser, poloxamer-188 (Shur-Clens™, ConvaTec, Skillman, NJ), was devised to remove bacterial contaminants from the wound without tissue toxicity.³ This wound cleanser has successfully decontaminated wounds in more than ten million patients without a single reported toxic reaction. A more concentrated solution of poloxamer-188 forms a gel that incorporates antibiotics for prevention of burn wound sepsis. The Argyle™ Edlich Gastric Lavage Kit has been used throughout the world to remove blood clots and poisons from patients' stomachs.⁴ Endoscopic

surgical gastrostomy was first devised by his team of physicians as a safe technique of tube feeding.⁵ A more reliable Gram stain procedure was developed to accurately identify bacterial pathogens in infections.⁶ Studies of the biomechanical performance of powder-free and latex-free examination and surgical gloves have identified superior glove products that have allowed more than 100 hospitals to abandon the use of dangerous glove powders.⁷

Dr. Edlich's book, *Medicine's Deadly Dust*,⁸ is a meticulously detailed report documenting the life-threatening dangers of powders from surgical and examination gloves. On September 24, 2008, Dr. Edlich teamed up with eleven other gifted health professionals to submit a Citizen's Petition to the US Food and Drug Administration to ban cornstarch powder on medical gloves.⁹ Because the Food and Drug Administration was slow to make a final decision banning the dangerous cornstarch powder on medical gloves, he submitted a review article to *Annals of Plastic Surgery* on the subject.¹⁰ As this team of surgeons and scientists made revolutionary advances in surgery, they helped transform the field of surgery into a discipline in which decisions are made on the basis of the results of reproducible, well-designed clinical and experimental studies. Dr. Edlich's research programs on the treatment of burn wounds have been complemented by the largest epidemiological study on burn prevention sponsored by the US Department of Health and Human Services. The study demonstrated the important role of liquid accelerants as a major causal factor of burn injuries.¹¹ On the basis of these studies, public education programs were initiated to end these preventable injuries.

A specialist in research on the biology of wound repair and infection, he is a coauthor of seven books and more than 800 scientific articles and chapters on these subjects. In 2000, Dr. Edlich received the Harvey Stuart Allen Medal from the American Burn Association in recognition of his significant contributions to burn care.

Emergency Medical Services

From 1971 until 1982, Dr. Edlich was Director of the Emergency Medical Service at the University of Virginia Hospital. He teamed up with his colleague and friend Dr. Ernst Attinger, Professor and Chairman of Biomedical Engineering, to develop a com-

prehensive emergency medical system in the Commonwealth of Virginia. With the aid of grants from the Robert Wood Johnson Foundation and the US Department of Health and Human Services, they championed the development of basic and advanced life-support training for physicians, emergency medical technicians and paramedics;¹² a telemetered medical system for emergency care; a rape crisis center;¹³ a crisis center for psychiatric emergencies; and the Pegasus Flight Operations, which is celebrating its 25th anniversary. Working with Governor John Dalton, Dr. Edlich was instrumental in the designation of Level I Trauma Centers in the Commonwealth of Virginia. He served voluntarily as the physician technical advisor for emergency care for Washington, DC, Maryland, West Virginia, Pennsylvania, and Virginia under the guidance of Dr. David Boyd, who served as Director of Emergency Care Operations for the Department of Health and Human Services. In recognition of Dr. Edlich's leadership in developing emergency medical systems, he received the Distinguished Service Award from the Department of Health and Human Services (DHHS). In 2008 Dr. Edlich was the recipient of the James D. Mills Award, the highest academic honor given by the American College of Emergency Physicians.¹⁴

Realizing the importance of partnerships between the University and industry, Dr. Edlich championed the development of the North Fork Research Park. This initiative transformed a 504-acre cow pasture into a modern industrial park. When he convinced MicroAire® Surgical Instruments to move its company from California to the North Fork Research Park, the University of Virginia built streets and a sewer and water system for the entire park. In recognition of Dr. Edlich's vision of a modern industrial park in Charlottesville, the University named the street entrance to this park *Edlich Drive*.¹⁵

Rehabilitation Medicine

After the development of the first poison control center at the University of Virginia, Dr. Edlich soon learned from a mother who was deaf about her unsuccessful attempts at contacting the poison control center regarding the ingestion of pills by her daughter. Because the poison control center and hospital did not have a teletypewriter (TTY) for the deaf, she was unable to enlist the help of the staff at the poison control center. Since the University of Virginia

hospital did not have adequate funds to buy a TTY, Dr. Edlich enlisted the help of Dr. Jerry Falwell, of the Thomas Road Baptist Church in Lynchburg, Virginia. Reverend Falwell and Dr. Edlich were committed to creating access for the deaf community to hospitals and community services. They teamed up to develop the National Crisis Center for the Deaf. This center provides access for the deaf community to emergency care and community services throughout our country.¹⁶

Dr. Edlich became a champion for the enforcement of the Americans with Disabilities Act (ADA) regulations. His complaints to the US Department of Justice have successfully removed architectural barriers to persons with disabilities in the Majestic Theatre in New York, Hotel Macklowe in New York, the Newark International Airport, and the Charlotte-Douglas International Airport. His strong advocacy for accessibility has made the University of Virginia a model of accessibility for people with disabilities. Recognizing that his own hospital as well as other hospitals had numerous architectural barriers to people with disabilities, he transformed the University of Virginia Medical Center into a barrier-free center that complies with ADA standards. In an effort to ensure that all hospitals comply with ADA, he is now working with the US DHHS Healthcare Financing Administration to incorporate ADA compliance review as part of its certification process. Realizing that all patient care involves a comprehensive rehabilitation program, he championed the establishment of a Department of Rehabilitation Medicine at the University of Virginia Health Science Center.

Discussion

As a teacher, Dr. Edlich is a popular speaker whose addresses are remembered by members of the University and professional societies. In 1985, he gave the Kennedy Lecture to the Society of Academic Emergency Medicine. In 1987 and 1992, the graduating class of medical students of the University of Virginia asked him to deliver their baccalaureate address. He delivered the commencement address to the graduating nursing students in 1993. In recognition of his commitment to teaching, the University of Virginia Alumni Association honored Dr. Edlich with its Distinguished Professor Award. Dr. Edlich was the recipient of the Commonwealth of Virginia's

Council of Higher Education's Outstanding Faculty Award in 1989. His work was honored by the Southeastern Society for Plastic Reconstructive Surgery's first prize for surgical research, the Virginia Surgical Society's Bigger-Lehman Award, and the University Association of Emergency Medicine's President's Award. A member of Alpha Omega Alpha and the Raven Society, he received the Hal Jayne Award from the Society for Academic Emergency Medicine for his academic excellence in 1989. In 1991, Dr. Edlich received the Thomas Jefferson Award, the highest academic honor presented by the University of Virginia. The Sigma Theta Tau International Beta Kappa Chapter presented him with its community service award in 1995. Also, Lafayette College presented the George Washington Kidd Class of 1876 Award to Dr. Edlich for achieving distinction in his career in medicine and teaching.

Through the generous support of friends and colleagues, endowments were established for the Richard F. Edlich Chair in Plastic Surgical Research, the annual Richard F. Edlich Medical Student Research Award in Emergency Medicine, and the Scientist of the Year Award from the University of Virginia Patent Foundation. During a meeting with President Clinton in the Oval Office on January 8, 2000, Dr. Edlich convinced President Clinton to increase funding for scientific research by the largest amount in this generation, to prevent and cure illnesses¹⁷. In November 2001, Dr. Edlich was invited to continue his medical career in the Pacific Northwest. His work with Dr. William B. Long, III, has been a unique experience in which Edlich has been inspired by Dr. Long's enormous contributions in developing the first Shock Trauma Center in the Pacific Northwest, modeled after the R Adams Cowley Shock Trauma Center in Maryland.¹⁸

Like his mentor Dr. Wangenstein, Dr. Edlich views his role as a teacher to be similar to that of a cheerleader for his many students and colleagues. Through his progeny, which includes more than 2000 students as well as myself, he will inherit eternity. I predict that Dr. Edlich's leadership will enhance the scope, breadth, and dimension of the *Journal of Environmental Pathology, Toxicology, and Oncology*.

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References

1. Edlich RF. In memoriam: a tribute to Dr. Owen H. Wangensteen, the greatest teacher of surgery during the 20th century (1898-1981). *J Surg Res.* 2001 Apr;138(2):241-53. Epub 2007 Feb 2.
2. Rodeheaver GT, Spengler MD, Edlich RF. Performance of new wound closure tapes. *J Emerg Med.* 1987 Nov-Dec;5(6):451-62.
3. Bryant CA, Rodeheaver GT, Reem EM, Nichter LS, Kenney JG, Edlich RF. Search for a nontoxic surgical scrub solution for periorbital lacerations. *Ann Emerg Med.* 1984 May;13(5):317-21.
4. Edlich RF. A gastric lavage assembly for rapid evacuation of the stomach. *Am J Dig Dis.* 1971 Feb;16(2):160-2.
5. Edlich RF, Prevost MV, Tsung MS, Ritchie WP Jr., Wangensteen OH. Transilluminated distention gastrostomy: a preliminary report of a simplified method employing an illuminated gastric catheter. *Surgery.* 1967 Sep;62(3):488-51.
6. Magee CM, Rodeheaver G, Edgerton MT, Edlich RF. A more reliable gram staining technique for diagnosis of surgical infections. *Am J Surg.* 1975 Sep;130(3):341-6.
7. Jackson EM, Arnette JA, Martin ML, Tahir WM, Frost-Arner L, Edlich RF. A global inventory of hospitals using powder-free gloves: a search for principled medical leadership. *J Emerg Med.* 2000 Feb;18(2):241-6.
8. Edlich RF. *Medicine's Deadly Dust.* Arlington, VA: Vandamere Press, 1997.
9. Edlich RF, Long WB 3rd, Gubler KD, Rodeheaver GT, Thacker JG, Borel L, Chase ME, Cross CL, Fisher AL, Lin KY, Cox MJ, Zura RB. Citizen's Petition to Food and Drug Administration to ban cornstarch powder on medical gloves: Maltese cross birefringence. *Am J Emerg Med.* 2009 Feb;27(2):227-35.
10. Edlich RF, Long WB 3rd, Gubler KD, Rodeheaver GT, Thacker JG, Borel L, Chase ME, Fisher AL, Mason SS, Lin KY, Cox MJ, Zura RD. Dangers of cornstarch powder on medical gloves: seeking a solution. *Ann Plast Surg.* 2009 Jul;63(1):111-5.
11. Cox MJ, Hwang JC, Himel HN, Edlich RF. Severe burn injury from recreational gasoline use. *Am J Emerg Med.* 1996 Jan; 14(1):39-42.
12. Buck R, Attinger E, Stone D, Geolot D, Edlich RF. The training of the emergency medical technician. *Va Med Mon (1918).* 1976 Apr;109(4):271-3, 276.
13. Talbert S, White SD, Bowen JD, Stephens LM, Mapstone SJ, Spisso KR, Edlich RF. Improving emergency department care of the sexual assault victim. *Ann Emerg Med.* 1980 Jun;9(6):293-7.
14. Edlich RF. Dreams, teachers, and legislation. *J Emerg Med.* 2010 Nov;39(5):652-4.
15. Bill TJ, Woods JA. Edlich drive: a metaphor for the Edlich tradition. *J Emerg Med.* 1997 Jul-Aug; 15(4):525-30.
16. Compton MV, Lattin-Souder M, Walsh WM 3rd, Sanders E, Stier D, Eyre PJ, Spyker DA, Edlich RF. An improved emergency telecommunications system for the deaf. *Compr Ther.* 1982 Jun;8(6):3-5.
17. Edlich RF, Pine SA. The quest for the cure of all chronic illnesses: a wake-up call from the President of the United States. *J Emerg Med.* 2000;19: 281-285.
18. Edlich RF. A tribute to William B. Long Jr. and William B. Long III: a celebration of their revolutionary contributions to trauma care. *J Long Term Eff Med Implants.* 2005; 15(5):439-466.

The Evolution of Emergency Medicine

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In this manuscript, I will outline three specific evolutionary achievements in the delivery of emergency and trauma care, followed by caveats on what prevents an emergency and trauma system from achieving optimal goals and maintaining them. First, I will review the emergence of the specialty of emergency medicine under the guidance of Dr. James Mills, and outline the steps he took to establish the specialty in acute care hospitals. Second, I will discuss the heroic career of Dr. R Adams Cowley, a cardiothoracic surgeon who took some of the principles of cardiac resuscitation and surgery and rapid military evacuation of the wounded from the battlefield, and applied them to the resuscitation and transport of the severely injured trauma patient to a fully prepared and equipped trauma center, and also created an organized approach to trauma care in Maryland. Third, I will provide an overview of the subsequent development of a comprehensive emergency medical system in the Commonwealth of Virginia. Finally, I will emphasize what prevents good public health policy regarding emergency medical and trauma care, and some of the changes that must be made to ensure that the Commonwealth of Virginia and other states provide optimal care for their citizens through their emergency medical care and trauma systems.

KEY WORDS: emergency medicine, trauma, surgery, Golden Hour

Introduction

Dr. James D. Mills, a general practitioner, saw the need for a physician with medical knowledge focused on medical emergencies and resuscitation dedicated to the hospital emergency room. He left his general practice and formed a full-time emergency practice group.¹ Dr. Mills' training and experience prepared him for a leadership role in medicine.² He served as a line officer in the Navy for four years (1941-1945) during World War II before entering medical school at the Washington University. His military service to our country became a life-defining experience. His additional three years of service in the Navy as a physician (1950-1953) showed him an organized approach to emergency care that was not available to the injured civilian, confirming that the chances for survival would be better in a combat zone than on the average city street. Because the military had a coordinated system of emergency care, he watched how skilled emergency medical teams changed a catastrophic injury into a life-transforming opportunity. After leaving the Navy at age 36, he started a practice in family medicine in Alexandria, Virginia, and was very involved in community service, becoming a member of the Board of Directors of Alexandria Community Health Center in 1956, a position he held for the next 18 years.

Within seven years after starting his practice, Jim was a recognized medical leader. He was elected President of the Medical Staff of Alexandria Hospital in 1961, which provided him with a unique overview of the entire hospital's healthcare delivery system. The dissatisfaction expressed by the patients treated in the hospital's emergency department caught his attention.³ "The public has come to look upon the emergency department as the community medical center where any man may come with any complaint, at any hour of the day or night, and expect prompt and courteous attention his due."

His emergency department was staffed then by rotating interns, residents, and nurses, with the backing of the attending staff. As attrition and turnover of the resident staff increased over time there were efforts made to supplant this service with various models. "One solution was to call the medical staff to serve in rotation. This was met with less than enthusiasm by doctors who had put in more than 60 hours a week in our practice."

In 1961, Jim then identified a different solution for this healthcare problem: staff emergency depart-

ments with physicians trained and credentialed in Emergency Medicine. Jim enlisted the help of three powerful problem-solvers to launch a revolutionary change in medicine. He and three of his physician colleagues, actively engaged in private practice, agreed to relinquish their practice and become full-time emergency department physicians. He recruited physicians in family medicine who were respected as doctors, who had taken on leadership roles in the hospital, and who were his close personal friends. It is remarkable that these pioneers in emergency medicine (Jim Mills, John McDade, Chalmers Loughridge, and William Weaver) remained together in emergency medical practice for their entire professional careers.

In 1963, Jim reported the 15 months' experience of his emergency medical coverage plan in the *Virginia Medical Monthly*.³ He indicated that, "The doctors of the emergency department continue to enjoy the cordial relations with their confreres they had in private practice. The staff members of the several services have been most helpful in their essential backing of the emergency department. The doctors of the community have learned that the service can help them with their patients during busy office hours, evenings off, or nights, with the assurance that their own doctor-patient relationship will be preserved...the 12-month patient load has increased 14% over the previous year."

When the American Medical Association highlighted the Alexandria plan in their news bulletin, national attention focused on this new health professional, the full-time emergency medical physician. Jim's innovation was a giant step ahead of the previous staffing either with interns and residents, or with rotating members of the attending staff.

With the need for and efficiency of around-the-clock skilled professional care in the emergency department demonstrated, the next step in the evolution of this new medical specialty was the specialized training of physicians whose career choice was in emergency medicine. In other words, residencies were needed in emergency medicine that would provide trained and board certified physicians for staffing emergency departments throughout the USA and other countries.

The following is the history of how this next step evolved. Dr. John G. Wiegenstein in Michigan became aware that some physicians, such as James D. Mills in Virginia, had started to practice solely in emergency departments.⁴ Others, in Pontiac,

Michigan, were contracting to provide emergency department coverage with part-time physician help. A physician, Dr. Eugene Nakfoor, informed Wiegenstein that he wanted to form an emergency medicine group to provide staffing at St. Lawrence Hospital in Michigan. The two proceeded to visit Dr. John Rupke who had set up an Alexandria-type plan in western Michigan. Wiegenstein was well aware of the need for education to provide emergency care and sought out training in emergency medical services and courses in critical care and trauma. In 1968, Wiegenstein, Rupke and six other emergency physicians from Michigan met in Lansing and formed the first national emergency medical organization, The American College of Emergency Physicians. Wiegenstein was elected as the first Chairman of The American College of Emergency Physicians. Before the inauguration of this organization, he wisely invited Dr. James D. Mills to be a member of the Board of Directors.

As emergency medicine began to develop as a discrete specialty, there was a need to train the physicians who were converting themselves to this new practice. The first emergency medicine residency was founded at the University of Cincinnati in 1970.⁵ As President of The American College of Emergency Physicians from 1971 to 1973, Jim Mills championed the development of certifying boards in emergency medicine. He served on the Board of Examiners from 1976 until 1988, and was appointed as President of the Board in 1986. Within 28 years, Jim Mills was able to realize his professional dream: a modern emergency department whose certified and well-trained emergency medical physicians expeditiously and effectively treated their patients with courtesy and compassion. By 1978, as a result of Jim's pioneering efforts, 30 university programs offered formal residency training programs in emergency medicine. The graduates of these programs entered active practice of emergency medicine and were in great demand to upgrade the quality of emergency service.

Today, the American College of Emergency Physicians represents more than 26,000 emergency physicians and is the largest and most influential organization representing the specialty. The history of The American College of Emergency Physicians is inextricably linked with the development, recognition and specialization of emergency medicine in the United States. The College is headquartered in Dallas and has 53 chapters representing each state, the District of Columbia, Puerto Rico and physi-

cians employed by the military and other government agencies. There are 216 residency training programs including those at the University of Virginia Health Sciences Center, Eastern Virginia Medical School and the Medical College of Virginia.

Jim Mills recognized that the part-time coverage of hospitals' emergency departments with interns and residents, often with little attending supervision, did not provide the emergency patients with optimal care, and that patients and their families were dissatisfied with the service. He foresaw that a new healthcare professional was necessary. He and a few of his colleagues were willing to commit themselves to developing and concentrating their knowledge in all types of emergency medical problems to become those new professionals, providing a new service for their hospital community. In mid career, Jim Mills changed professions to demonstrate the need for a new healthcare specialist and modeled that innovative concept. Not only did he model it, he made the effort to describe his experience with this concept in the medical literature. Other healthcare professionals recognized that this new concept made sense and looked to Jim for guidance on how to establish similar programs for their hospitals. Jim carried the torch for emergency medicine as a specialty and aided its incorporation into the university academic teaching programs and helped to create a national organization to accredit the new specialists and focus on setting national standards.

Jim planted the seed from which a new specialty grew. On April 25, 1989, he succumbed to an unusually aggressive myelogenous leukemia, leaving the specialty of emergency medicine as a legacy for us all.

The Emergence of an Organized Approach to Civilian Trauma Care: The Contributions of Dr. R Adams Cowley

In their book *Shock-Trauma*, two acclaimed journalists, Jon Franklin and Alan Doelp, tell the whole story of how Dr. R Adams Cowley, a professor and chairman of cardiothoracic surgery at the University of Maryland, saw the poor care trauma victims received in the state of Maryland and sought to do something about it.⁶ He started by obtaining a US Army grant to study shock, and the reasons patients die from shock. The Army funded a two-patient critical care unit where intense monitoring and research was done on patients in shock referred to the unit by doctors

who could offer no other options for these patients. With the initial successes, Cowley applied for federal funding to expand the clinical research unit to include 16 ICU beds, two operating rooms, a floor for hyperbaric chambers to treat advanced shock, and research laboratories.

With the matching funds from the State of Maryland, Cowley acquired medevac helicopters, manned by the Maryland State Police, to rapidly bring trauma patients from the scene of the accident (bypassing urban traffic gridlocks) to the operating rooms at the Shock Trauma Center. Ill-equipped and inadequately staffed emergency departments with little or no support from the hospital's surgical specialists were bypassed for a trauma center staffed by surgical specialists and anesthesiologists, interested and specially trained in traumatic injury, immediately available to treat the patient. These basic concepts would revolutionize how trauma care would be delivered in Maryland and other states.

Who was Dr. R Adams Cowley, known affectionately as "R A.," and how did he become interested in this huge public health problem of traumatic injury? Raised in rural northern Utah on a ranch, R.A. was familiar with the impact of traumatic injury on working families and the community. This led him to pursue a career in medicine. He did his undergraduate studies at the University of Utah in Salt Lake City (1936-1940), and his medical education at the University of Maryland School of Medicine (1940-1944) and supported his family during those years by working in his off hours.

He began his surgical residency in 1945 at the University of Maryland and was interrupted in 1946 by military service, which had considerable influence on his surgical career. As Chief of Surgery for a field hospital, he was sent to Europe soon after World War II ended. R A.'s military service became a life-defining experience.⁷ He soon discovered that there was an abundance of surgical opportunities in the war's aftermath with civilians being assaulted and injured throughout Europe. In 1946, he worked under virtual wartime conditions in the operating rooms of his hospital in Mourmalon, France. As he gained experience, he became Chief of General Surgery of the 98th General Hospital in Munich, Germany. R A. repeatedly witnessed the military emergency medical system's ability to change a catastrophic accidental injury into a life-transforming opportunity. Cowley acknowledged his debt to the army, which had intro-

duced him to the field of trauma, a subject that would be the focus of his entire professional career at the University of Maryland where he became a skilled cardiothoracic surgeon.

After the war, he joined the faculty at the University of Maryland and initially pursued a career in open-heart surgery, made possible by the cardiopulmonary bypass machines invented by Gibbon, DeWall and Lillehei. Patients who were dying of shock and heart failure could survive a surgical intervention with the aid of these life-support devices. It was an exciting time for the pioneering surgeons in adult and congenital heart surgery. Some of the brightest surgical talents in the USA were attracted to this field.

However, the memories of his military experience and observation about trauma led Dr. Cowley to pursue a second career: trauma care and the development of trauma systems of care. Even though cardiothoracic trauma is relatively rare in civilian populations, R A. saw a sharp contrast between trauma care in the military hospitals and that provided in civilian hospitals in the United States, and even in his own university hospital. Most noticeable were the delays in care provided to the trauma patient, which could result in their bleeding to death. Emergency medical technicians (EMT) were trained to "stabilize" patients at the scene of the accident, similar to patients with heart attacks. EMTs treating trauma patients can most often control external bleeding with compression dressings and tourniquets, but they cannot stop or control internal bleeding. Patients bleeding internally need immediate surgery to stop bleeding. Emergency departments at most hospitals are staffed by non-surgeons. On nights and weekends, the surgeons and anesthesiologists need to be called in from home to do emergency surgery. The delay and lack of experience and preparation can be fatal.

Reflecting on R.A.'s military career, Franklin and Doelp reminded their readers of the sharp contrast in care between an emergency department with no trauma experienced surgical team immediately available and that of a trauma center, where all the resources are immediately available to save a life. They included a memorable comment about Cowley's disdain for emergency department care of the trauma patient.⁸ "The God's truth is that most emergency rooms are awful. I get into trouble every time I say that and some miserable [individual] quotes me in the newspaper, but it's true. Even today you live or die depending on where you have your accident, because in most places

they take you to the nearest hospital.” Cowley’s disdain for the incompetence of emergency department care of trauma patients was deep and abiding. After being trained as an open-heart surgeon, he knew that the lives of trauma patients could only be saved in an operating room in a shock trauma center. RA. had clearly identified a goal for his life: “I want to save the lives of injured Americans.”

Origin of the First Shock Trauma Center

Cowley’s concepts of trauma care began in the mid 1950s when his studies of shock in animals demonstrated the importance of immediate care.⁹ He focused on the trauma patient who had lost blood, suffering an extreme drop in blood pressure. When he took a quart of blood from a laboratory dog, Cowley caused the animal to develop shock. By returning the blood to the animal quickly, the animal would recover. If the animal remained in shock more than one hour, “the golden hour,” death came slowly and inevitably to all dogs. Dr. Cowley had developed a simple but revolutionary concept: he related the duration of shock directly to life expectancy. He concluded that the trauma team must restore the patient’s blood pressure within that “golden hour” to save the patient’s life.

Cowley built upon the classic foundation of Walter B. Cannon’s book, *Traumatic Shock*, published in 1923.¹⁰ Cowley’s experience grew out of his investigations in combat surgery during the battles in France during World War I. His early clinical studies of shock in the trauma and critically ill patient were funded by an Army Research Development contract, which later supported the development of Cowley’s two-room Clinical Shock Trauma Research Unit in 1961. Skeptics referred to it as the “death lab.” Franklin and Doelp celebrate the courageous attitudes of Cowley’s surgical residents who coordinated the care of the patients in this two-bed trauma research unit. “We were the black birds of the hospital, man,” commented Dr. David Boyd, one of Cowley’s residents. “Whenever we showed up on the wards, the nurses would dive for their charts to see who was in shock. Whenever we were around, someone was dying.”¹¹

Patients dying from all types of shock were transferred to this research unit only as a last resort. Death with dignity was still an unrecognized concept and the patient’s family was usually begging the physician to do anything. From the beginning, half the patients

brought to the “death lab” did not die. These results made Cowley ecstatic. He realized the potential impact of his trauma care on the 50,000 people who were dying on the highways each year, more than 800 in his own state of Maryland. If he had a big enough trauma center, he knew he could save at least half of these lives.

In 1966, the Committee on Shock and the Committee on Trauma of the Division of Medical Sciences of the National Academy of Sciences/National Research Council wrote a white paper, *Accidental Death and Disability: The Neglected Disease of Modern Society*. This document was prepared after three years of deliberations and is considered to be the inaugural event in what was to become a sustained effort sponsored by government to control accidental injury as a health problem.¹² This publication outlined the enormous magnitude of the personal and financial losses due to accidental injury to include the tragedy of death among the young, the burden of disability and the economic costs of billions of dollars. The authors emphasized that the scope of the problem was even more concerning because the public had developed an apathetic attitude toward trauma care.

Ignoring the public’s sentiment of indifference, the authors outline a broad program of action that included training, education, and research to improve the expertise and fund of knowledge available regarding treatment, in particular, emergency medical care. The authors believed that there could be a cooperative effort between medical professionals and the lay public with the federal and state governments providing guidance and allocating funds for these projects.

This revolutionary manuscript made recommendations for the care of seriously injured patients. It pointed out that optimal treatment must begin in the prehospital phase with ambulance services adhering to established standards, including vehicle construction and credentialing of fully trained ambulance attendants. It emphasized that radio communication technology was essential for a timely dispatch to call for help. It spoke to the need for the emergence of a new specialty of physicians with special training in immediate care, providing additional support to Jim Mills’ dream of having a specialty of emergency medicine.

This document asked that outside agencies with regulatory authority categorize hospital emergency and trauma capabilities. Four categories were described that varied from first aid facilities to fully capable trauma centers able to manage all trauma

patients. The authors believed all hospitals and care providers should be held accountable for patient outcomes. The development of registries of valid and reliable data would ensure that information from autopsies would be available to examine the outcomes of care. Moreover, the report pointed out that investment in prevention of injury through sponsored research, public education, or government regulation would have enormous benefits in reducing healthcare costs. Most important, the paper pointed out that the budget for injury research was inadequate and it recommended the establishment of a National Institute of Trauma within the US Public Health Service.

Congress appropriately responded to the accidental death and disability report by enacting legislation, the National Highway Safety Act of 1966 (Public Law 89-564), which had a profound effect on the treatment of the trauma patient in America.¹³ The Department of Transportation was given the responsibility to allocate money as well as instruction to implement the law. Because one of the goals of the legislation was to reduce injury to occupants in motor vehicle accidents, research sponsored resulted in the development of effective car safety devices. The bill also identified systematic changes intended to improve the care of injured patients, including expanded capability for radio communication and use of helicopters for medical evacuation of injured patients to hospitals. Funding of ambulance services was integrated into the national highway traffic safety program. Maryland, Florida and Illinois were the major benefactors of the federal programs funded by the National Highway Safety Act of 1966. These states revolutionized the development of regional emergency services programs, including trauma systems. Under the leadership of R Adams Cowley of the Maryland Institute for Emergency Medicine, the University of Maryland Hospital joined together with the Maryland Police Aviation Division in a revolutionary transport program. It will come as no surprise that implementation of this first trauma system in Maryland caused a dramatic reduction in the mortality rate of seriously injured patients.¹⁴

Most trauma centers today consist of a few beds in either the emergency department, or an intensive care unit (ICU) that are dedicated to trauma patients. Hospital administrators will call it a trauma center. This arrangement results in fundamental changes in the care given in the emergency department or ICU. However, R A. realized that the mission of the emer-

gency departments and the ICUs were different than that of a true trauma center. The emergency department must be geared to a wide variety of patients with different conditions, most of which are not life-threatening. The average ICU is structured to provide postoperative care to patients receiving major surgical procedures or needing support for heart and/or lung failure.

R A.'s concept of a trauma center was neither an emergency department, nor an ICU. His trauma center had a resuscitation area, combining the best of the emergency department and the ICU, always prepared to immediately receive and treat the most critically ill and injured patients. The severely injured trauma patient arrives at the hospital undiagnosed and untreated with his survival at stake. R A.'s trauma center had the ability to provide resuscitation as well as diagnostic and therapeutic measures for most critical situations, and to continue such care until that patient's condition stabilized. R A.'s cardinal rule was "treatment before definitive diagnosis."

In his trauma center, all necessary lifesaving services, diagnostic and ancillary equipment, were brought to the patient; the patient was not transported throughout the hospital for diagnosis and treatment. Treatment was immediate, and operations were performed on an instant's notice. Rehabilitative measures began on admission and were a fundamental, continuous part of care to minimize disability. In his trauma center, there was no waiting. Resuscitation, stabilization, definitive care, and rehabilitation were all a part of his trauma center, and they all began on the patients' arrival.

Working with the Maryland State Police Aviation Division, he developed an efficient and cost-effective air medevac helicopter program. Helicopters were based across the state, and the patients were flown directly to the Shock Trauma Center in Baltimore from almost any corner of the state in less than one hour, the "golden hour" for treating the trauma patient. Simultaneously, R A. created a communication network that became the first comprehensive statewide communication system to provide radio contact between the scene of an emergency, ambulances, hospitals, specialty referral centers, medevac helicopters, and fire department central alarms, with both voice and telemetry capabilities. Cowley's growing emergency medical system won support from the State and the University of Maryland, and after reorganization in 1973, became an autonomous institute within the

University of Maryland (Maryland Institute for Emergency Medical Services Systems or MIEMSS). This Institute combined the Shock Trauma Center with the statewide Emergency Medical System program.

The development of his modern trauma center within a university setting was not accomplished without difficulties. Resistance to a physically and administratively separate facility was intense. R A. had to overcome opposition of healthcare professionals and administrators who were reluctant to relinquish control of the trauma center. R A. surmounted these enormous obstacles and demonstrated the significant potential of a modern trauma center in a university setting that reached the goals of excellence of care at all levels, standards of therapy developed through research and education, dissemination of new knowledge, and provision of care systems for the community.

On the morning of April 13, 1971, the tide of resistance dramatically changed when Governor Marvin Mandel was fortuitously involved in trauma care.¹⁵ His long-time friend James P. Mause was involved in a serious auto accident and a land ambulance took him to the nearest hospital in Frederick, Maryland. Because the doctors at the hospital were unable to care for his injuries, he was transferred to a larger hospital in nearby Hagerstown, MD. When Mandel was alerted to the severity of his friend's injuries, he immediately intervened by taking a State Police helicopter to the hospital in Hagerstown to see his friend. In a scene dramatically pictured in Franklin and Doelp's book *Shock-Trauma*, "He was lying flat" Mandel remembers. "I walked over to him and spoke to him. He was conscious, but he could hardly do anything but move his arm a little. I'll never forget that as long as I live. He indicated distinctly that he wanted a pad and pencil." Slowly, with agonizing effort, Mause wrote, "Marvin, please, I want to live." Mandel called Cowley to transfer Mause to the Shock Trauma Center where Cowley's team saved Mause's life. Cowley later took the Governor on a tour of the Shock Trauma Center. Realizing the enormous benefit of the Center, the Governor became a strong advocate for Cowley.

Despite Cowley's clinical achievements in the care of the trauma patient, there was still continued resistance to patient transfer as well as criticism of Cowley's efforts. When this criticism wended its way to the Governor's office, Mandel commented, "I think medical politics are much tougher than politics as I know it. Much tougher. They tried to make Dr. Cow-

ley look like an individual who'd gone berserk, who was doing everything counter to what the medical profession would want to see. And, oh, my God, they had meetings all over the place, denouncing him."¹⁶

When the Chairman of the Department of Surgery at the University of Maryland threatened the autonomy of the Shock Trauma Center, Governor Mandel interceded and signed an executive order that created the Maryland Institute for Emergency Medical Services and separated the Center from the Department of Surgery. With the skillful use of his friendship with Mandel, Cowley sold the concept of the Shock Trauma Center to the State of Maryland. He had successfully affected a societal transformation program that would allow all patients in Maryland to gain the benefit of care in a modern trauma center. Ultimately, he directed the entire emergency medical system of Maryland as well as a new \$50 million, eight-story, 135-bed trauma center until his retirement in 1989.

Most Maryland physicians and surgeons who were practicing when Cowley was introducing and refining these new approaches to trauma care, and who knew of the outcomes of that type of treatment, are convinced that he is the most successful trauma surgeon in the world, an achievement that the Governor, the Maryland legislators, and the public recognized appropriately by naming the new modern shock trauma center the R Adams Cowley Shock Trauma Center at the University of Maryland. Of the patients treated there in 2003, 4,759 (95%) were transported from the scene of injury at the request of local fire services and 252 (5%) were transported between hospitals to obtain a higher level of care. In 2003, Maryland's emergency medical service community commemorated the transport of the Maryland State Police Aviation Division's 100,000th patient. In continuous operation since March 19, 1970, the Maryland State Police Program is the oldest existing medevac program for the transport of civilians in our country.

The authors Franklin and Doelp concluded their book *Shock-Trauma* with the following hopeful message. "Perhaps most important of all a steady stream of trauma resident fellows come each year to Shock Trauma to study under Cowley, and when they leave the young surgeons often take Cowley's convictions with them. Across the country, veterans of shock trauma are fighting the same battles that Cowley fought and for the same reasons."¹⁷ One of Dr. Cowley's gifted

residents was Dr. William B. Long, III, who pioneered the development of the only American College of Surgeons Verified Level I Trauma Center for children and adults at Legacy Emanuel Medical Center in Portland, Oregon, and who was instrumental in helping Oregon develop the first statewide trauma system in the Pacific west coast states.

Initially, federal funding supported only development of Emergency Medical Service (EMS) systems in all 50 states, a program created and overseen by Dr. Dave Boyd, who became the Director of EMS for the Federal Department of Health, Education, and Welfare. Dr. Boyd was a fellow at the Center for the Study of Shock and studied patients on the two-bed ICU research unit Dr. Cowley founded at the University of Maryland Hospital.

Professional organizations, such as the American College of Surgeons Committee on Trauma (AC-SCOT), began to advocate standards for trauma center categorization. The Committee on Trauma of the American College of Surgeons had a leadership role in trauma system development. With its publication of the first edition of *Optimal Hospital Resources for Care of the Seriously Injured* in 1976, the Committee on Trauma provided a landmark document of the essential characteristics of trauma centers and stressed that trauma centers must operate in the context of a trauma system.¹⁹ This *Optimal Hospital Resources* document and its subsequent editions are always cited by state authorities designing trauma systems and its recommendations are utilized to form state standards for trauma centers and trauma systems.

As emergency medical service systems and trauma systems have evolved in each state with and without federal funding, the principle of a coordinated approach to trauma care established by Dr. Cowley in the State of Maryland has not been replicated in other parts of the country. The role of aeromedical services range from limited to non-existent in many states, and land ambulance politics have limited the use of rapidly available, medically staffed helicopters in many others. In San Francisco, a city ordinance prevents medical helicopters from landing at major trauma centers in the city, necessitating the transfer of a critically injured patient to a level one trauma center by land ambulance. The stated reason is noise abatement. The “golden hour” of life concept is not available to the trauma patients being transferred to San Francisco General Hospital from outside San Francisco.

Many other states do not have statewide coordinated air and ground advanced life support services with access to a separate and dedicated trauma facility. This lack of a statewide coordinated advanced life support program has resulted in unnecessary loss of lives.

Origin of Emergency Medical Systems in the Commonwealth of Virginia

I accepted the position of Acting Director of the Emergency Room at the University of Virginia Health Sciences Center in 1974. At that time, I was Assistant Professor of Plastic Surgery and had no specialized clinical and educational emergency healthcare experiences that allowed me to be selected for this position. I had no formal training in either prehospital care, emergency care, or trauma care. The lack of awareness about this public health problem and the resources needed to address it led to no other applicants for this position when my predecessor resigned. Ironically, the University of Virginia faculty was worried that my academic credentials would cause me to focus more on research than clinical care in the emergency room. I emphasize the term emergency *room*, because that was all the University Hospital provided me to see emergency patients. By appointing me as Acting Director, the University was implying that I could be easily terminated from the position if I did not fulfill responsibilities that were never changed from Acting Director to Director, because the University was continually concerned that I was making too many changes in the emergency room.

On my first day as Acting Director, I thought it would be appropriate to gather together the entire staff involved in caring for the nearly 35,000 patients treated annually in the emergency room. The staff consisted of second-year surgical residents, third-year medical residents, full-time emergency medical nurses, and one hospital administrator. I had no supervisory control over the staff because these individuals reported to their own administrative department heads.

I scheduled a meeting with this wide range of health professionals who treated this large number of patients, personally contacted each of the individuals and posted announcements of the first conference. I anticipated participating in a dynamic conference in which they would share visions about the future of the emergency room. When I arrived at 8 am for the

conference, I was surprised that no one was there. After waiting for 15 minutes in the empty room, I set out to find out why no one showed up. The medical and surgical residents were sleeping because they had been awake all night taking care of patients. The nursing staff was busy preparing for a change in shift. The hospital administrator could not be found.

After this learning experience, I immediately reflected on the sage advice of my mentor, Dr. Owen Wangenstein, Chairman of the Department of Surgery at the University of Minnesota Health Sciences Center, in selecting a medical career.²⁰ There were two important considerations. First, select a field that is important to humankind and that provides an opportunity to save lives. Second, choose a field in which relatively few health professionals see opportunities for revolutionary advances in care. It would appear that the directorship of the University of Virginia Emergency Room had met all of Dr. Wangenstein's criteria for an ideal job. Armed with this sage advice, I learned the ropes by using a system of crisis management to approach the problem of emergency medical services systems and trauma care.

With regard to the prehospital system, I found that most rescue squads were poorly trained and driving antiquated vehicles with no radio communication system. In 1974, the minimum requirement for certification of ambulance attendants was the American Red Cross Advanced First Aid Course, which was generally considered inadequate for those who were required to render care to persons who were seriously ill. Most rescue vehicles had citizen band radios that allowed them to communicate to the University police, who would then relay the message to the emergency room by telephone.

Upon the arrival of my first transport of an accident victim to the emergency room, I was surprised to find a patient who had been injured in an automobile accident, was not breathing, but resting comfortably on a soft stretcher. The 42-year-old male patient had cold, purplish-colored skin and no detectable vital signs. He must have been dead for at least 30 minutes. When I asked the rescue squad if they had performed cardiopulmonary resuscitation (CPR), they indicated that they had no training in this technique. It was even more disturbing to find that none of the hospital personnel in the entire facility had any formal training in CPR. I had to acknowledge, however, that the nursing and administrative staff had an expeditious and organized plan to transfer the patient from

the hospital to the morgue. They knew exactly how to encircle the large toe of the corpse with a label, allowing proper identification and transfer to the funeral home. I was horrified by my hospital staff's lack of interest in and knowledge of emergency medicine. Our emergency room had no life-saving equipment and staff capability; one could observe that we served merely to transport the dead patient to the funeral home. These memories caused me many sleepless nights and became my first life-defining experience in emergency medicine.

This was only the first of many frightening life-defining experiences involving other emergency clinical care services offered by my hospital. My reflection of these services are the best illustrated by recounting several tragic and potentially preventable personal losses. In the crisis intervention service, a medical resident had answered a telephone call from a patient who was threatening to kill himself. The suicidal patient had organized a detailed plan, ensuring that he would be successful in his effort. He told the resident that he had placed a microphone next to his heart so that he could localize the audible noises of his heartbeat to ensure an accurate shot from his gun. The resident pleaded with him not to take this desperate action and offered to get immediate psychiatric consultation. After carefully writing down the patient's name and telephone number, he immediately called the psychiatric resident, asking him to contact the suicidal patient. The psychiatric resident, who was also busy interviewing a patient for admission to the hospital, delayed returning the call for at least five minutes. His delayed call to the patient was not answered. Forty-five minutes later, a call was received from the police that this same patient had a self-inflicted bullet wound to his heart. The emergency room staff had failed to save this frightened patient's life. This warning gave the nurses ample time to find another toe tag. The patient was dead on arrival and expeditiously transferred to the morgue.

Prior to 1976, the poison control system consisted of a drug card file that was updated daily by one of the clinical departments. A resident had received a telephone call indicating that a 4-year-old child had unwittingly swallowed 25 tablets of Tylenol®. The resident immediately called the pharmacy asking them for a drug dose study to determine the risk to the child. The pharmacy immediately called back, indicating that this dosage of Tylenol® was potentially life-threatening, and recommended the child come

immediately to the emergency room for treatment. The embarrassed resident was unable to contact the patient's family because he had not written down a name or telephone number.

Sexual assault patients were being routinely interviewed in the hallway of the emergency room, providing the patient no confidentiality. There were no guidelines for patient care or physical evidence recovery kits. Psychosocial support of the distressed individual was not provided by the staff. I had the perception that the distressed patient who was sexually assaulted was treated in the same manner as a college student complaining of a toothache. The hospital administrative staff and young residents were numb to the plight and psychological trauma of the sexually abused.

Handwritten medical records were completed only by physicians who ignored the nurses' notes stapled to the back of the patients' medical records. Critical patient information provided by the nurses about a patient was lost in this confused system of care. After reading the previously mentioned description of care given to patients, the reader might reasonably argue that the patients should not pay for their clinical care.

I soon learned that the inadequacy of the health-care system in the emergency room was not the reason for the absence of a billing system. Receptionists did not have a computerized billing system and were not allowed to accept any cash payments for care. When I suggested the novel approach of billing patients for emergency medical services, the hospital administrator explained to me that the university would be reimbursed by the state government for the cost of free care. Realizing the ineptitude of the infrastructure of the emergency room, I asked that my office in plastic surgery be relocated to the emergency room. Because the hospital had no funds for my relocation, they suggested I seek grant funds to pay for renovating my office.

As Acting Director of the University Hospital Emergency Room, I inherited a clinical care system that ignored the illness or injury as well as the soul of the patient. This emergency healthcare system had to be reformed so that it treated disease and listened to the patients. At the entrance to the emergency room, the staff had positioned a large, white board with each treatment room listed along the top of the board. A box outlined below the designated room that was used for writing pertinent information regarding

each patient. Patient identification was by illness or injury and may have included sexual assault. Chairs were positioned below the white board for patients who had not yet been interviewed, waiting to be escorted to the designated room. The white board was adjacent to the entrance of the emergency room so emergency room staff as well as strangers could have an overview of the challenging clinical problems.

I hoped that a colleague or friend would join me in improving the emergency room situation, as well as its emergency medical system, and help transform it into a dynamic and caring lifesaving system. It was as if God had sent an angel to my rescue. On a busy Saturday evening in 1975, one of the licensed practical nurses, Shirley Talbert, asked to speak to me privately, regarding our care of sexual assault victims.²¹ She spoke in a gentle and kind manner that did not reflect her exasperation with the incompetent care. She began by providing a simple overview of her concerns. "Dr. Edlich, the care of sexual assault victims in this Emergency Room is outdated, inappropriate, ineffective, and dangerous. We act as if we are in the dark ages of medical care. For instance, both the police and the physician interview sexual assault victims in the hallway. Moreover, we don't use an evidentiary recovery kit for obtaining legal specimens. Follow-up of these patients is nonexistent. I would recommend that we make some immediate changes." Because Shirley was so concerned, motivated, and knowledgeable about this subject, I asked her to head a sexual assault task force that would develop standard protocols for treating these patients. Moreover, I asked that she identify other interested nurses who would become familiar with established treatment protocol. She pointed out that they were going to need considerable help from the police as well as attorneys to devise these protocols. She emphasized that the emergency room must have a demonstrated commitment to the care of these patients by allocating one treatment room to conduct confidential interviews with these patients as well as other assault victims. I agreed to her request and enlisted the help of the chief of police, John Bowen, as well as a dynamic attorney, Susan White. Both of these individuals helped organize protocols for the emergency care of the sexual assault victim, including guidelines for patient care, discussion of police investigations, written consent forms, and physical evidence recovery kits.

After developing these new protocols, I approached hospital administration regarding allocation

of a separate room for confidential interviews. The space for the outdated emergency room was limited, and there was immediate reluctance to any space reallocation. After gaining support from all departments in the hospital, I persuaded hospital administration to reallocate this space. When this final decision was made, I believed that one of the administrators had severe misgivings about the new plan. After the room was stripped of cabinets and shelves, the tile floors were thoroughly cleaned in preparation for the change. My intuition about hospital administration's reluctance to accept the changes was confirmed when I asked the question, "Where can we get a couch and two chairs?" The administrator responded, "We have no money available for furniture."

Fortunately, I was able to slowly make changes in the culture of the emergency room and the hospital that allowed improvements in emergency care. The hospital selected a new head nurse, Sue Loud, who was an emergency nurse practitioner. In addition, the hospital had hired a new director of nursing, Helen Ripple, who was a champion for excellence in patient care. She was a product of a devout Catholic family that was committed to service to the disadvantaged. She had a new and innovative managerial style that allowed her to make immediate decisions. These decisions were based on her loving concern for patients in the hospital. When I approached Helen regarding the sexual assault center without furniture, she had an immediate solution. Pointing at the furniture in her office, she said, "Use any or all of the furniture in my office!" While expressing my appreciation for her generous offer, I questioned her as to how she planned to replace it. She responded, "Those folding metal chairs in the hallway will be perfect."

The opening of the Crisis Center for Sexual Assault Victims had numerous repercussions. First, the Charlottesville community began to view the emergency room as a safe retreat for sexual assault victims in which they would receive superb medical care that was coordinated with an effective legal investigation. Shirley Talbert expanded the nurse liaison role by identifying a safe haven for the patient after discharge as well as being present with the victim in any subsequent court appearance. This supportive environment for the sexual assault victim subsequently brought victims out of the closet. Their numbers were so great that the nurse liaison could no longer assume sole responsibility for their housing as well as the other services she provided. Realizing the enormous mag-

nitude of the problem, the community established a shelter for victims of sexual assault and domestic violence. In addition, a non-profit organization with volunteer trained counselors was organized to provide patient advocates in the emergency room as well as following discharge from the hospital. The Virginia legislation related to sexual assault was outdated and irresponsible and had to be changed to protect the assault victim. It was blanketed with rules that protected the man against a "vengeful woman." Consequently, the victim was thoroughly cross-examined by the defendant's attorney about her past sexual activities. The victim had to prove that she resisted the rape to the utmost, despite threats to her life. Another feature of the antiquated rape legislation was the draconian penalties for the convicted assailant. Juries often acquitted, rather than send the defendant to prison for 20 or more years. Subsequently, the Commonwealth of Virginia enacted modern legislation, similar to that of the Michigan comprehensive rape law reforms. In this legislation, the victim cannot be cross-examined regarding her past sexual history. A victim who alleges that she was raped may still have her reputation within the community come to issue, but testimony about specific sexual acts is expressly prohibited. The victim does not have to prove that she physically resisted the assault. Furthermore, sentencing of the assailant is more flexible with graded penalties, based on the violence of the crime. In May 1979, Shirley Talbert gave a keynote address before the University Association for Emergency Medicine in Orlando, Florida, outlining her organized effort to improve emergency department care of the sexual assault victim.²¹ Her speech was especially notable in that she was the only licensed practical nurse to ever address this emergency physician academic organization. In addition, she was the recipient of a community service award from the Charlottesville Board of Supervisors.

As I reflected on this experience, I was certainly pleased that they have improved the quality of care for sexual assault victims. However, I was saddened that I was not aware of the treatment of women in the emergency room until Shirley awakened me from this anesthetized state. During the last 20 years, I have grown to realize that the problems facing women in our emergency room in Charlottesville are only the small tip of a giant iceberg that is blocking women from equal status in the country.

These early life-defining experiences in the emergency room helped me define my goal: *develop a*

model emergency medical system for the University of Virginia Hospital as well as the Commonwealth of Virginia. Faced with numerous life-threatening crises in emergency medical care, I began to search within the massive university medical bureaucracy for other angels to help me. I was delighted that my search was successful as I found two more unsung heroes at the university who assisted me in dramatically changing emergency care from a fatalistic, disorganized service to a vibrant, structured emergency healthcare system. One was Dr. Ernst Attinger, who was the Director of Biomedical Engineering. Ernst was both a physician and engineer; he was a skilled clinician whose talents in biomedical engineering complemented his innate sensitivity to clinical care.²² His department had already established contractual relationships with the hospital in which his staff would provide quality assurance testing for medical devices used in the hospital. In addition, he had already established a computerized information system that could be potentially used in the emergency room.

Another unsung hero was Dr. Richard Crampton, Professor of Cardiology, who had clear visions of the potential benefits of prehospital care in saving lives of patients with heart attacks.²³ He had developed an effective alliance with one rescue squad, the Charlottesville-Albemarle Rescue Squad, which was willing to develop a prehospital lifesaving plan for patients with heart attacks. Dick first designed this prehospital system so that the rescue squad would pick up a medical resident and transport the resident to the patient with signs of a heart attack. His embryonic program was beginning to save patients' lives. He doggedly pursued his interests in prehospital cardiac care during the subsequent 20 years, and he became a recognized leader in this field.

During my tenure as Acting Director of the Emergency Room, major developments resulted in dramatic improvements in emergency medical care. Cognizant of the need for improved emergency service in the country, the Robert Wood Johnson Foundation decided in the early 1970s to authorize a nationwide competitive program to encourage communities to develop regional emergency medical systems. In 1974, Dr. Attinger and I were awarded a grant to implement an emergency medical system in the Thomas Jefferson Planning District 10, the five-county geographic catchment area for the University of Virginia Hospital. The grant program, which ended in 1977, focused on access of the public to

the emergency medical system by the 911 telephone number, training of rescue squads, and development of a radio communications system for rescue squads in this five-county region. The number 911, designated for public use throughout the United States to request aid from fire, police, or rescue agencies, had already been installed in Nelson County in 1969 after Hurricane Camille.²² By late 1976, adjacent Greene and Fluvanna Counties had this emergency telephone service. Installation of this system for the more populated regions of Albemarle County and the City of Charlottesville was accomplished in 1984. The development of this 911 telephone system eliminated the 40 telephone numbers for the different police and fire departments and rescue squads in the five-county area. Consequently, we had developed a system that allowed immediate access for hearing individuals into the emergency medical system.

The Department of Transportation's National Highway Safety Administration allocated sufficient funds to develop a training course for rescue personnel that prepared them to care for the sick and injured using basic life-support techniques. This 81-hour training program was pilot-tested at Piedmont Virginia Community College in Charlottesville in 1975, after which it was offered to other rescue squads in the region. Successful completion of the course allowed the rescue squad personnel to be certified as emergency medical technicians-ambulance (EMT-A). In 1983, this training program became the minimum training requirement for the rescue squad personnel for certification by the Virginia Department of Health. The first training program at Piedmont Community College was an Edlich family event. I taught and attended all of the classes and completed certifications as EMT-A. During the mock field tests, my three children, Elizabeth, Richard, and Rachel, volunteered to participate as "casualties."

A radio communications system was designed and implemented by Frank Hunter, Assistant Professor of Biomedical Engineering, which allowed trained rescue squads to communicate with the University of Virginia Medical Center and Martha Jefferson Hospital, as well as with each other. Today, there are three advanced training programs for rescue squads certified by the Virginia Department of Health. The objectives of the emergency medical technician-shock trauma (EMT-ST) training program devised by Diana Rockwell, an emergency medical nurse at the hospital, were to have the students understand

the dangerous consequences of significant traumatic injuries and selected medical emergencies, as well as to teach the appropriate therapeutic intervention to stabilize the patient's condition.²³ The emergency medical technician-cardiac (EMT-C) course focuses on emergency care of the heart attack patient and teaches the student to perform cardiac monitoring and defibrillation, the use of electric shock to correct irregular heartbeats. The emergency medical technician-paramedic course provides the highest level of training for prehospital personnel.

The passage of the Emergency Medical Service Systems Act (EMSS) in 1973 was the next major development. This program, led by Dr. David Boyd, authorized \$185 million over 10 years and provided the awarding of grants and contracts for development of emergency medical systems throughout the United States. The passage of this Act provided the mechanism and funds for communities in Virginia to develop regional emergency care systems that were modeled after our successful regional system in Charlottesville. Because the system was receiving national recognition, Dr. Dave Boyd, head of Emergency Medical Services of the federal Department of Health and Human Services, asked me to serve as one of his eight physician-technical advisors to assist state governments in designing and implementing their emergency medical systems. I was assigned to assist Maryland, West Virginia, Virginia, Pennsylvania as well as Puerto Rico, to guide these geographic regions to implement their emergency medical systems. Because Dr. Boyd had developed a conceptual plan for an emergency medical system, my job was relatively easy: to advise enthusiastic communities on implementing plans to improve emergency medical care.

Realizing that the emergency medical system in our country should benefit the President of the United States, I worked with Secret Service to develop an emergency care plan for the President of the United States. When President Reagan was shot, the Secret Service agent immediately took President Reagan to a trauma center rather than to an emergency department. The trauma surgeons were ready for the arrival of the President and saved his life.

The only challenging part of my voluntary position was to advise Dr. Cowley regarding his exemplary statewide system that was a model for the world. Realizing that Dr. Cowley was the father of organized trauma care, I willingly accepted the role

of student and listened carefully to Dr. Cowley's retelling of his extensive experience at the Shock Trauma Center. As I carefully reviewed the organized trauma program, I realized that the Commonwealth of Virginia could benefit by replicating Dr. Cowley's coordinated program.

Dr. Cowley and I spent long hours discussing the many obstacles to implementing a modern trauma care system. In Virginia, I had encountered the same resistance by administrators and surgeons to developing an organized trauma care program that Dr. Cowley had overcome in Maryland. On the basis of the pivotal support of Governor Mandel for Dr. Cowley's trauma care program, Dr. Cowley suggested a simple remedy to my problem: enlist the help of the Governor of Virginia. It was fortuitous that the Virginia First Lady, Eddy Dalton, and Governor John Dalton were both sympathetic and appreciated the benefits of organized care. When the First Lady joined me on a tour of the Shock Trauma Center in Baltimore, Dr. Cowley provided a clear vision of the components of a successful trauma care system which I later promoted nationally. Eddy Dalton was sufficiently impressed by what she saw and heard in Maryland to have an impassioned discussion with Governor Dalton, who directed Virginia's Department of Health to designate regional trauma centers in 1981.

For hospitals to be designated as trauma centers by a governmental agency such as the Department of Health of the State of Virginia, the hospital has to apply to the state department of health to have a site visit by trauma experts who verify the hospital's commitment of resources and organization as detailed in the American College of Surgeons (ACS) trauma center criteria to develop a responsive program that provides specialized care to the trauma patient.²⁴ Designation as a Trauma Center had some influence on the University of Virginia Hospital. There was a positive change in attitude toward the trauma patient by the entire hospital staff, especially surgical and emergency personnel, but also including hospital administrators, teachers, scientists, and support personnel, and gave impetus to the in-house reorganization necessary to develop a multidisciplinary trauma service. However, I must emphasize that I did not lobby effectively for a separate clinical trauma service in the hospital that would allow patients to be admitted directly to the trauma service rather than being seen initially by emergency physicians. Trauma surgeons should be present at the time of the trauma patient

arrival and be prepared to offer immediate surgery if necessary. Many trauma centers operate as a single unit by having the emergency physician and trauma surgeon work together as a team to resuscitate the patient, but the trauma surgeon is the team leader, and makes all surgical decisions.

Today, designation of trauma facilities is often done at the state level. The ACS does not participate in any designation process. However, the ACS has established both a trauma center and system verification process to assist hospitals (and systems) in evaluation and improvement of trauma care and to provide information regarding institutional capability, performance, and system development to aid those who are responsible for developing and maintaining these systems.

The federally supported program championed by Dr. David Boyd allowed me to implement other important programs in emergency medical care. An emergency first aid guide was written and published in the community telephone books so that each household with a telephone would have an understanding of first aid treatments for the sick and injured. An emergency medical nurse practitioner program was temporarily established in the Nursing School that became a fertile training ground for nurses who would assume leadership positions in medicine. In addition, staffs were trained to provide a coordinated, organized approach to the care of the victims of sexual assault, their treatment now guided by modern, updated practices of care. In addition, psychosocial support was arranged for each patient. A computerized poison information system was developed at the University of Virginia Hospital that replaced the antiquated card file. Trained staff members could now answer each call and ensure optimal care. Trained psychiatrists and social workers staff the crisis intervention center and provided immediate and continued support for all patients. The University of Virginia Hospital employed two full-time nurses to provide continuing education courses for the 18 rescue squads that transported patients to the hospital. A life-support training center was established to teach the faculty and residents the psychomotor skills to care for trauma patients as well as those who have had a heart attack. These trauma and cardiac care programs were accredited educational programs that were instituted in the medical center. Recently, these programs were expanded to include continuing education programs involving the care of the injured

or sick child. The cardiac training program has been made available to the fourth-year medical students.

With the exception of an emergency air transportation system, I naïvely thought that all central Virginia now had immediate access to the finest medical care. This momentary naïve celebration of my accomplishments was shattered when I received a handwritten note from a disgruntled patient. This note became another life-defining experience. It opened with a cry for help: "To whom it may concern: I had a frightening experience that I want to share with you. While I was cleaning dishes in the kitchen, I was shocked to see my five-year-old daughter swallow the last portion of a six-ounce bottle of cough syrup. I immediately grabbed the bottle from her hands, thinking that she had swallowed an overdose of medications that may be life-threatening. Using my teletypewriter, I telephoned your poison control center and got no response. Fearing for my daughter's life, I asked my next-door neighbor to drive us to the Emergency Room at the Hospital. Your doctors and nurses were wonderful and assured me that my daughter was in no danger and that the cough syrup would have no side effects. They even showed me some childproof caps for bottles that even I had a hard time opening!" The presence of an interpreter who was skilled in sign language considerably facilitated the communication. However, she was shocked to learn that the University of Virginia Hospital did not have a TTY (teletypewriter) in its emergency room or hospital. While she thought that the University Hospital had wonderful emergency care for the hearing in its hospital, she believed that they had forgotten the deaf. This short letter burst my bubble as I realized that my modern emergency department was not responsive to the deaf community. I wrote her an apologetic note, promising that the University Hospital would have TTY's in the emergency department as well as the hospital. As per usual, I naïvely made this promise without speaking to the hospital administrators. Because I purposefully tried to remain uninformed about hospital finances, it was easy for me to make promises without regard to budgets. Through grants from the federal government and the Robert Wood Johnson Foundation, as well as the annual state funding for the hospital, more than \$4 million had been spent to develop the modern emergency medical system in the Commonwealth of Virginia. Consequently, I thought that the \$350 needed to buy a TTY would be a drop in this large financial bucket.

I had to develop a written proposal for hospital administration to support the cost of purchasing the TTY for the emergency room as well as those for the hospital. I wrote the report with the same naïveté of a college student who was submitting a manuscript to his teacher. Because I had not met or treated individuals with severe hearing impairments, I had no perception of the plight of the deaf community. To familiarize hospital administrators with the importance of the project, I went immediately to the library to search for information on the TTY system that could be included in my report. This report began by describing the origin of the TTY so that the administrators would be better able to understand its purpose. It went something like this: “a major development in telecommunications enabled deaf individuals to use standard telephone technology to transmit messages between teletypewriters. In 1964, Robert Wiebrecht, a deaf physicist, developed a modem to convert teletypewriter code into frequency or tones that are transmitted over telephone lines. When receiving, the demodulator circuits of the modem convert the tones into the digital signals used by a teleprinter. More than 75,000 deaf people have the special teletypewriter/telecommunications devices (TTY/TDD) that allow them to send and receive messages by telephone and gain access to emergency care. This telecommunications device must be immediately purchased and available for use in the emergency room and poison control center. In addition, a TTY should be available for patients with hearing impairment to be used in their hospital rooms. The retail cost for this device is \$350.”

My proposal was sent expeditiously to hospital administration with the expectation that I would receive an A for its content and \$700 for TTYs in the emergency department and poison control center. One week later, the hospital administrator gave me an F and no check, explaining that the funding for my request would be placed in next year’s proposed hospital budget. While the eloquent letter from the deaf mother had touched my heart, my scholarly manuscript on TTYs had not opened the hospital coffers. Dismayed by the failure of the hospital to implement this life-saving system for the deaf, I telephoned the hospital administrator and reiterated the importance of the TTYs to the hospital and even threw in the medical and legal implications of the failure to have TTYs. My pleas fell on deaf ears...

My disappointment with the hospital’s lack of support for the deaf community, coupled with the weight of my promise to the distressed mother that my hospital would serve the deaf community, compelled me to search for another avenue to solve the problem, one that would also help deaf individuals throughout the State of Virginia: the development of a statewide emergency telecommunication system for the deaf. I sent in a grant request to the Office of Emergency Services located in the central government of the Commonwealth of Virginia. I provided a detailed description of the system that could be available at a bargain price of \$25,000. A computer-aided emergency telecommunication system for the deaf would be housed in the poison control center and serve as a relay station for all TTY calls from the deaf. My grant for an innovative emergency program for the deaf community throughout the state was turned down by the Office of Emergency Services with the explanation that such a statewide program would be better coordinated by its Richmond office. It is important, however, to point out that my rejection letter did not include any promise by the office that such a program would be implemented.

Undeterred by this bad news, I then pursued yet another avenue for solving this urgent problem: garnering funds for the development of a nationwide emergency telecommunications system for the deaf. With the appropriate modifications, I expanded my proposal, describing a computer-aided emergency telecommunications system for the deaf for the entire country at a bargain price of only \$250,000. I sent this grant request into the Office of Emergency Services of the Department of Health and Human Services of the federal government. I did not have any unrealistic expectations of successful grant approval because this division had planned to be terminated; moreover, my friend, David Boyd, had resigned from the office. Consequently, my next letter of rejection from the federal government came as no surprise. Despite this growing list of rejections for my plans for an emergency telecommunications system for the deaf, I remained blissfully optimistic that I would achieve my new goal of developing a nationwide system and keep my promise to the deaf mother. I realized that the reasons for my unsuccessful attempts to assist the deaf community were caused primarily by the fact that I was communicating with decision-makers who were unsympathetic to the plight of the deaf community. I had to find an individual or organization that listened to the deaf.

I found the answer to my search in a hotel room in Chicago.²⁵ The reason for my visit to

Chicago was the annual meeting of the American College of Surgeons. Because my academic career had required increasing numbers of trips, I felt considerable loneliness, missing my wife and three children living on our 18-acre farm in Albemarle County, twelve miles from the university. On Sunday morning, I decided to try to find some spiritual consolation watching a televised church service. During this telecast, I confessed that I did not recognize the name of the minister, but was impressed by his strong voice, commitment to beautiful music and God. What mostly caught my attention was a small box on the lower right-hand corner of the screen in which a woman was using sign language to communicate the minister's message to the deaf while the sermon was being delivered. The credits at the end of the telecast provided the answer to my quest when they identified the service as being broadcast from the Thomas Road Baptist Church in Lynchburg, Virginia.

When I returned home to Charlottesville, I called the church to learn the name of this televangelist. The operator at the church informed me that Reverend Jerry Falwell was the minister whose Sunday services were televised throughout the world as the "Old Time Gospel Hour." I immediately made an appointment with Dr. Falwell to share my dream about a National Crisis Center for the Deaf.

Fully aware of the importance of this meeting, I brought with me respected colleagues from the University who could eloquently vouch for the importance of the mission. Dr. Will Spradlin, Professor and Chairman of the Department of Psychiatry, and Dr. Daniel Spyker, Director of the new computerized Poison Control Center, agreed to join me for the mission. We met Reverend Falwell in his office at the Thomas Road Baptist Church. After introducing my colleagues to Dr. Falwell, I outlined my plans for a computerized emergency telecommunications system for the deaf in the United States. When I began to discuss the need for such a program, Dr. Falwell asked me politely to expedite my discussion because Dr. Falwell reminded me that he had long been a champion for the deaf and had been committed to their access to his ministry using signing as well as TTYs. I then indicated that this communication center would be housed at both Dr. Falwell's university and at the University of Virginia. Staff from Dr. Falwell's university could provide spiritual counsel to

the deaf, while the University of Virginia would coordinate emergency services. I handed Dr. Falwell a proposal for the telecommunication centers. Without reading it, Dr. Falwell asked the big question: "How much money will you need?" I answered, "\$250,000." Dr. Falwell immediately responded, "I can support your proposal. Let's get started as soon as possible."

In June 1981, two years after I read the deaf mother's impassioned plea, the National Emergency Medical Telecommunications System for the Deaf was established. The deaf community had 24-hour, toll-free access to this Center, which was staffed by emergency personnel especially trained to meet the communication needs of the deaf. The computerized system expedited exchange by automatically sending out questions. The staff member monitors this interchange between the deaf caller and the microcomputer and interrupts as needed to elicit additional information or clarify responses. A computerized directory of emergency services facilitated referral to an appropriate public agency. After identifying the agency, the staff member telephoned the agency, requesting a response to the caller's emergency situation. Within the first month, the staff responded to calls from 20 states as well as the District of Columbia.

I was very surprised by the different types of calls. Sixty-one percent of the callers used the emergency service for information referral. Because deaf individuals had no access to banks, utility companies, or directory assistance, they viewed themselves as isolated from society and in desperate need of assistance in conducting the business of their everyday lives. While hearing individuals telephone a bank about checks, loans, and mortgages, banks, like hospitals, had no TTYs to receive calls from the deaf community. Consequently, the deaf community appropriately judged calls to a utility company or bank to be an emergency. Only 24% of the callers requested life-saving emergency care. The remaining callers (15%) requested that our staff relay information to members of the hearing community. The type of information relayed included contact with employers to give notice of illness, personal business inquiries, and notification of death of a family member. Their joint efforts clearly demonstrated that the deaf community throughout the country was isolated from society and subject to discrimination because of their disability. This unconscionable and deplorable situation was finally resolved with the passage of the Americans with Disabilities Act (ADA) in 1990. Because this Act

required that each local telephone system design an emergency response system for the deaf, the need for our pilot program ended.

Their attempts to improve communication and safety for the deaf community facilitated the vast changes implemented by the ADA. In watching this revolution take place, I learned a very important lesson. The pursuit of a dream that changes lives is so grand it cannot be contained. Its power radiates, takes on a life of its own, and provides the blueprint for other changes and contributions in areas that were never identified from the outset.

As I participated in developing revolutionary advances in the emergency medical system in the Commonwealth of Virginia as Acting Director of the Emergency Department, I was notified by a friend that the University of Virginia planned to terminate my position as Acting Director. As I considered this potential crisis in my life, I again followed the advice and guidance of my beloved mentor, Dr. Owen H. Wangenstein. He had indicated to me that if my neck was on the guillotine for an extended period of time, ask my friends for help. Consequently, he immediately called the director of the University of Virginia Health System and said that Dr. Edlich wants to develop emergency medical systems in our country. Let him achieve his dreams. When the director heard Dr. Wangenstein's impassioned plea for me, the director said immediately that I should be allowed to achieve this goal. When Dr. Wangenstein called me and told me this good news, I knew that my position as acting director was safe.

Because I was part of Dr. David Boyd's medical adventure, he thought it should be documented in the scientific literature. Dave expressed some reluctance in collaborating in this endeavor because he was too busy changing the nation's healthcare system. Fortunately, in 1983, he agreed to edit with me and Dr. Sylvia Micik, Associate Professor of Clinical Pediatrics at the University of California School of Medicine in San Diego, the landmark publication, *Systems Approach to Emergency Medical Care*.²⁶ In the preface to this book, it was pointed out that, "This book is of importance to EMS systems today as few, if any, regional EMS systems have yet to accomplish the task of completing a totally comprehensive regional EMS system." This prediction was verified by a report in the *Journal of the American Medical Association* in 1989 that acknowledged that only Virginia and Maryland had successfully implemented all components of a comprehensive

regional emergency medical system.²⁷ Today, the University of Virginia Hospital has a new Emergency Department with modern critical care facilities. A residency training program has been established to train future leaders in academic Emergency Medicine.

An important development in the Virginia emergency medical system has been the establishment of an emergency air transportation system. The emergency air transportation system began on a beautiful fall day in 1975 when the University of Virginia was contacted by a physician in Grundy, Virginia, requesting that the University of Virginia burn center accept a burn patient from its hospital. Because the ground transportation distance from Grundy to Charlottesville was more than nine hours, I knew that this seriously ill burn patient would die of shock during the long ambulance transport. Knowing that I could possibly save the patient's life if I had a plane to fly there and back, I rented a fixed-wing aircraft to fly me to Grundy. After gathering together appropriate lifesaving equipment, I began the first emergency medical flight for the University Hospital. I remember clearly the beautiful, spectacular adventure flying over the mountains of Virginia on such a magnificent day.

When I arrived in Grundy, I was met by an ambulance that transported me to the hospital. After stabilizing the condition of this desperately ill young man, they transported me and the patient back to the airport. The patient was accompanied by his father as well as a nurse from the Grundy hospital. I welcomed the father to fly with me, but the nurse was concerned that the father would have no place to stay in Charlottesville. The father assured me that he would be very comfortable sleeping in the lobby of the University Hospital. When the nurse from the Grundy hospital asked the father if he had enough money for food, he indicated that he did not have enough if his son's hospitalization lasted longer than a week. Without hesitation, she opened her purse and gave him \$40 to help him on his journey. This generous gift from the nurse exemplifies the gifts of love and affection that I have encountered from so many loving individuals during my travels through emergency medicine during the last 40 years. I transported the patient back to the hospital where the patient made an uneventful recovery. When I presented the bill for renting the plane to the Director of the hospital, the Director looked at me with considerable surprise and asked me if I planned to continue these rescue operations. I assured him that this first flight was just the beginning.

My prediction became a reality with the development of the Pegasus Flight Operations.

During its first 10 years of operation, Pegasus had transported 5,945 patients by helicopter and 1,393 patients by fixed wing.²⁸ In 1993, 571 critically ill patients were transferred by helicopter to the University of Virginia Hospital. The majority of the patients (68%) flown by helicopter were transferred from a referring hospital to the University of Virginia Hospital. The remaining patients (32%) were stabilized by the trained rescue squad at the scene of the accident and then transferred to the emergency department of the University of Virginia Hospital.

The fixed-wing air transport team made 205 flights. Of these, 135 flights involved the transfer of critically ill patients. In 70 other flights, the transplant team procured organ donations. The newborn ICU accounted for approximately 5% of the fixed-wing flights, as well as helicopter flights bringing critically ill babies back to the university's neonatal ICU.

I have tried to show, dramatically and graphically, how patients with life-threatening illnesses or injuries, who once would have died during transport to the nearest emergency department, are now being safely transported to Verified Level One Trauma Centers that are prepared to take heroic measures to save the patients' lives. Most of these survivors are rescued by a well-trained team of health professionals who gain little national recognition. However, when Christopher Reeve suffered a spinal cord injury after falling from his horse in nearby Culpeper, Virginia, every American celebrated his emergency medical and rehabilitation journey. It was indeed fortunate that his injury occurred after the implementation of this modern emergency medical system in the Commonwealth of Virginia.

As doctors, nurses, paramedics, pilots, and rescue squad volunteers save lives, they are faced with tremendous emotional pressures in their efforts to reverse the tide of violent death. Breathtaking in its immediacy, moving in its intimacy, and exhilarating in its message of hope, it has been an unforgettable saga of an emergency medical adventure that state emergency medical systems are still waging together. As I reflect on my career in Emergency Medicine over the last 40 years, I have had the unrivaled honor of championing the development of a model emergency medical system in the Commonwealth of Virginia that has saved thousands of lives.²⁹ The success of this emergency medical system is because of the talented members of the emergency medical team who

care for the patient from the time of injury until complete recovery. My professional career has truly been a joyful experience. I have ridden the winged horse Pegasus to a constellation in the stars. I am one of the luckiest people in the world to have been privileged to be part to this heavenly adventure.

Expanding Dr. Cowley's Dream

The organized approach to caring for trauma patients was introduced into the civilian setting by the innovative pioneer, R Adams Cowley.³⁰ His system in Maryland has the following 11 components: (1) a State Police Aviation Division that transports patients throughout the state, (2) trained paramedics at the scene of the accident as well as on the helicopter that will stabilize the patients en route to the Shock Trauma Center, (3) one central dispatch communication center in Baltimore that coordinates information between paramedics and the trauma center, (4) a Shock Trauma Center with a helicopter landing port on the roof of the building, (5) trained trauma nurses as well as trauma technicians to transfer the patient from the helicopter by stretcher to the resuscitation area. If there is a special complication, such as an airway problem, the anesthesiologist and/or trauma surgeon may meet the helicopter on the roof as well, (6) all trauma surgeons are board-certified in surgery with a certificate of added qualification in surgical critical care care for the critically ill trauma patients in the resuscitation area, (7) a CT scan and portable X-ray units in the admission area that aid in the diagnosis of the injury, (8) operating rooms adjacent to the admission area for repair of trauma injuries, (9) a surgical intensive unit to care for the trauma patient, (10) a team of specialty physicians trained in a wide variety of specialties that works as a multidisciplinary unit caring for the hospitalized patient, and (11) an ambulatory outpatient unit that allows the patient to be followed in the Center after discharge. Dr. R Adams Cowley incorporated each of these eleven components for an organized trauma center in Maryland. His legend in Trauma Care lives on!

Like so many other regions in our country, the Pacific Northwest urgently needs statewide aviation systems that transport patients throughout Oregon and Washington to one of the two designated Verified Level I Shock/Trauma Centers for children and adults, such as at Legacy Emanuel Medical Center in Portland, Oregon. These helicopter transport units

have immediate access to trauma surgeons working in the Legacy Emanuel Shock Trauma Center that is a separate functioning unit in the hospital. This separate trauma center has a separate trauma resuscitation unit with CT scan and portable x-ray units. Operating rooms are immediately adjacent to the resuscitation unit. It is my quest to have every citizen in the Pacific Northwest know about this Verified Level I Shock/Trauma Center led by the gifted trauma surgeon, Dr. William B. Long, III, President and Medical Director of Trauma Specialists, LLP.³¹

Working with Dr. William B. Long, III, it has been an exciting adventure. The trauma team has made revolutionary advances in healthcare. They helped pass legislation that requires lift equipment in all hospitals in the State of Washington to prevent back injuries in healthcare workers.³² We have developed operating room posters for the use of the double-glove hole indication systems that prevents the transmission of deadly bloodborne viral infections.³³ In addition, we have instituted the use of emergency medical examination gloves with a glove hole leakage rate of only 1% as compared to 4% glove hole leakage rate for the standard hospital examination gloves, at the emergency department and trauma center.³⁴ We have devised a website for Trauma Specialists, LLP, that has eight free continuing medical education courses sponsored by the Dannemiller Memorial Foundation that has not been incorporated into the Legacy Health Care System website for the past two years. In addition, there are no highway signs directing people to the trauma center or signs within the hospital, even

though I have personally had two *Trauma Center* signs framed and given to the Legacy Emanuel Administration. Finally, I have published an editorial on the use of car bumper stickers that can be attached to the car indicating that the injured occupants want to be taken to Legacy Emanuel Shock Trauma Center.³⁵ These bumper stickers have not been given to all of the Legacy Health System employees. Fortunately, I have two bumper stickers on my Dodge Caravan. Hope springs eternal that I can awaken the Legacy Health System and the citizens of the Pacific Northwest to the presence of this landmark Verified Level I Trauma Center for children and adults. This is my Quest!

Conclusion

As I accepted the James D. Mills Award from the American College of Emergency Physicians in 2008, I wanted to acknowledge the guidance and advice of three gifted physicians: Dr. James D. Mills, Dr. R Adams Cowley and Dr. William B. Long, III, for their guidance and advice in my efforts to develop comprehensive emergency medical systems in our country. As you may have guessed, I view each individual in my emergency medical journey as a teacher. In recognition of their enormous contributions to my life-saving career, I have given to each of them a copy of a picture developed by a graphic artist that identifies the six unique features of a teacher that have been highlighted by Dr. Owen H. Wangensteen, who is recognized as one of the best surgical teachers during the last century (Fig. 1). Dr. Wangensteen and I would

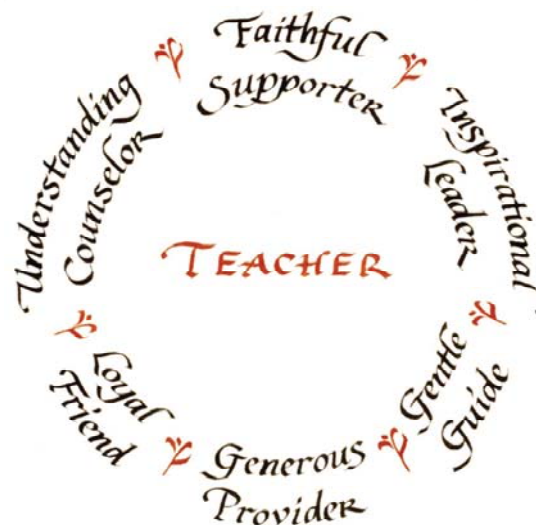


FIGURE 1. Six Unique Features of a Teacher

like each of our teachers to achieve their wonderful dreams that allow our country and world to be a safer and happier place to be. This is our Quest!

Acknowledgement

This is to acknowledge Samantha K. Rhoads, Holly S. Stevens, Jamie J. Clark, and Jill J. Dahlstrom, who have worked with me as Research Assistants, and whose goals have been to make dramatic improvements in healthcare in our country. I also want to acknowledge my mentor and gifted friend, Dr. Peter Rosen, for nominating me for the James D. Mills Award.

References

1. Edlich RF, Wish JR, Britt LD. An overview of revolutionary advances in emergency medical care in the United States. *J Long Term Eff Med Implants*. 2004;14(5):375-99.
2. Edlich RF. Profiles For Success. Lessons Learned in Teaching, Healing, Curing and Living. Arlington, VA: Vandamere Press; 1999. p. 54-57.
3. Mills JD. A method of staffing a community hospital emergency department. *Va Med Mon*. 1963; 90: 518-519.
4. Wiegenstein J. What, another milestone? The first steps in the founding of a specialty. *Ann Emerg Med*. 1997;30:329-33.
5. Somand D, Zink B. The influence of critical care medicine on the development of the specialty of emergency medicine: A historical perspective. *Acad Emerg Med*. 2005;12:879-83.
6. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p.1.
7. Edlich RF. Profiles For Success. Lessons Learned in Teaching, Healing, Curing and Living. Arlington, VA: Vandamere Press; 1999. p. 57-62.
8. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p. 17.
9. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p. 11-12.
10. Cannon WB. Traumatic Shock. New York: D. Appleton Co.; 1923.
11. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p.18-19.
12. Committee on Trauma, and Committee on Shock, Division of Medical Sciences, National Academy of Sciences/National Research Council (US). Accidental Death and Disability: The Neglected Disease of Modern Society. Washington: National Academy of Sciences; 1966.
13. Highway Safety Act of 1966, Public Law No. 89-564, 89 Stat. 3052.
14. Cowley RA, Hudson R, Scanlan E, Gill W, Lally RJ, Long W, Kuhn AO. An economical and proved helicopter program for transporting the emergency critically ill and injured patient in Maryland. *J Trauma*. 1973; 13:1029-1038.
15. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p. 146-147.
16. Franklin J, Doelp A. Shock-Trauma. New York: St. Martin's Press; 1980. p. 242-243.
17. Edlich RF. Profiles For Success. Lessons Learned in Teaching, Healing, Curing and Living. Arlington, VA: Vandamere Press; 1999. p. 63-67.
18. American Medical Association Commission on Emergency Medical Services. Categorization of Hospital Emergency Capabilities. Chicago: American Medical Association; 1971.
19. Committee on Trauma, American College of Surgeons. Optimal hospital resources for care of the seriously injured. *Bull Am Coll Surg*. 1976;61:15-22.
20. Edlich RF. In memoriam: a tribute to Dr. Owen H. Wangensteen, the greatest teacher of surgery during the 20th century (1898-1981). *J Surg Res*. 2007;138(2):241-53.
21. Talbert S, White SD, Bowen JD, Stephens LM, Mapstone SJ, Spisson KR, Edlich RF. Improving emergency care of the sexual assault victim. *Ann Emerg Med*. 1980; 9: 293-297.
22. Ricks TD, Whitehead WN, Stone D, Attinger EO, Edlich RF. Nine-one-one. *Va Med Mon*. 1976; 103: 268-269.
23. Rockwell DD, Crampton RS, Mapstone SJ, Grant JE, Edlich RF, Garvin JM, Miller KP. New in Virginia: the shock-trauma emergency technician. *Va Med Mon*. 1981; 108: 410-413.
24. Edlich RF. Virginia's trauma centers. *Va Med Mon*. 1984; 111: 106-107.
25. Compton MV, Lattin-Souder M, Walsh WM 3rd, Sanders E, Stier D, Spyker DA, Edlich RF. Computer-aided emergency telecommunications for the deaf. *Ann Emerg Med*. 1982; 11: 324-326.
26. Boyd DR, Edlich RF, Micik S. Systems Approach To Emergency Medical Care. Norwalk, CT: Prentice-Hall; 1983.
27. West JG, Williams MJ, Trunkey DD, Wolfert CC Jr. Trauma Systems. Current status-future challenges. *JAMA*. 1988; 259(24):3597-600.
28. Edlich RF. Riding Pegasus on a heavenly journey. *J Emerg Med*. 1995;13: (6) 811-814.
29. Edlich RF, Clapp AR. Evolution of emergency services in central Virginia. *Va Med Mon*. 1985; 112: 185-187.
30. Edlich RF, Wish JR, Britt LD. An organized ap-

- proach to trauma care: Legacy of R Adams Cowley. *J Long Term Eff Med Implants*. 2004;14(6):481-511.
31. Edlich RF. A tribute to William B. Long, Jr., and William B. Long, III: A celebration of their revolutionary contributions to trauma care. *J Long Term Eff Med Implants*. 2005;15(5):439-66.
 32. Edlich RF, Hudson MA, Buschbacher RM, Winters KL, Britt LD, Cox MJ, Becker DG, McLaughlin JK, Gubler KD, Zomerschoe TS, Latimer MF, Zura RD, Paulsen NS, Long WB 3rd, Boodie BM, Berenson S, Langenburg SE, Borel L, Jenson DB, Chang DE, Chitwood WR Jr, Roberts TH, Martin MJ, Miller A, Werner CL, Taylor PT Jr, Lancaster J, Kurian MS, Falwell JL Jr, Falwell RJ. Devastating injuries in healthcare workers: Description of the crisis and legislative solution to the epidemic of back injury from patient lifting. *J Long Term Eff Med Implants*. 2005; 15(2):225-41.
 33. Edlich RF, Wind TC, Heather CL, Thacker JG. Reliability and performance of innovative surgical double-glove hole puncture indication systems. *J Long Term Eff Med Implants*. 2003;13(2):69-83.
 34. Edlich RF, Winters KL, Martin ML, Long WB 3rd, Werner CL, Gubler KD. *J Long Term Eff Med Implants*. 2005;15(2):161-83.
 35. Edlich RF. Trauma center car bumper stickers for many patients receiving trauma care. *Am J Emerg Med*. 2008;26(3):371-2.

Postexposure Prophylaxis for Deadly Bloodborne Viral Infections

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The purpose of this report is to discuss management of operating room personnel who have had occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and human T-cell lymphotropic virus type I (HTLV-I). HBV postexposure prophylaxis includes starting hepatitis B vaccine series in any susceptible unvaccinated operating room personnel who sustain an exposure to blood or body fluid during surgery. Postexposure prophylaxis with hepatitis B immune globulin (HBIG) is an important consideration after determining the hepatitis B antigen status of the patient. Ideally, all operating room personnel should be vaccinated with hepatitis B vaccine before they pursue their career in surgery. Immune globulin and antiviral agents (eg, interferon with or without ribavirin) should not be used for postexposure prophylaxis of operating room personnel exposed to patients with HCV; rather, follow-up HCV testing should be initiated to determine if infection develops. Postexposure prophylaxis for HIV involves a basic four-week regimen of two drugs (zidovudine and lamivudine; lamivudine and stavudine; or didanosine and stavudine) for most exposures. An expanded regimen that includes a third drug must be considered for HIV exposures that pose an increased risk for transmission. When developing a postexposure prophylaxis regimen, it is helpful to contact the National Clinicians' Postexposure Prophylaxis Hotline, (888) 448-4911. Prevention should be a major consideration in postexposure prophylaxis with the use of the double-glove hole indication system by all operating room personnel.

KEY WORDS: hepatitis B, HBV, hepatitis C, HCV, human immunodeficiency virus, HIV, human T cell lymphotropic virus type I, HTLV-I

Introduction

Because surgical needles have a proven role in spreading deadly bloodborne viral infection, the surgeon must select surgical gloves that reduce the risk of accidental injuries during surgery.¹ A unique double-glove hole indicator system has been developed that reduces the incidence of needle puncture as well as provides a unique glove hole detection system that facilitates an initiation of postexposure prophylaxis. Postexposure prophylaxis consists of the following components: (1) treatment of exposure site, (2) evaluation of the type of exposure, (3) evaluation of the exposure source, (4) completion of the exposure report, (5) postexposure prophylaxis and (6) occupational exposure management resources. By following these comprehensive recommendations, the reader should be able to institute a program in his/her hospital that will reduce the frequency of deadly bloodborne viral infections.

Double-Glove Hole Puncture Indication System

Because surgical glove perforation provides exposure to viruses that can infect operating room personnel as well as the patient, Palmer and Rickett² examined the mechanisms and risks of surgical glove perforation in a hospital. In their study, 275 pairs of surgeons' gloves were collected from 100 consecutive operations. In 42% of the operations where glove damage occurred, the surgeon was aware of the needle perforation. It was surprising that in only 28% of the operations did the surgeons change their gloves because the surgeon was aware of the surgical glove needle puncture. Surgical glove puncture was unnoticed in 58% of the instances where it occurred. On the basis of this clinical study, Palmer and Rickett² indicated that a surgeon risks acquiring more than one hepatitis B infection per lifetime. In addition, they estimated that at least one in 1,500 surgeons is likely to be infected by the human immunodeficiency virus (HIV) during the next 35 years.

Because most surgical glove hole punctures go unnoticed for some time after perforation, Molnlycke Health Care (Norcross, GA) designed and manufactured a new double-glove hole puncture indication system called the Biogel® Reveal™ Puncture Indication System. This glove hole indication system was first developed for latex gloves. It consisted of a double-glove puncture indication system with the in-

ner glove uniformly colored green. Later, Molnlycke Health Care replaced the Biogel® Reveal™ Puncture Indication System with the Biogel® Indicator® Underglove that can be combined with a variety of Biogel® latex gloves as the outer glove. When the outer glove was punctured, the green inner glove immediately was exposed to the blood and other fluids in the operative procedure. After exposure to fluids, this double-glove puncture indication system developed the appearance of a darker green color around the outer glove puncture site, a warning to operating room personnel of the presence of glove puncture of the outer glove. This color change is an optical effect and does not involve release of dye or any other material. After noting this color change, the surgeon should remove all surgical gloves, wash hands and don a new double-glove puncture indication system.

The Department of Mechanical and Aerospace Engineering, University of Virginia, Charlottesville, VA (USA), was the first to measure the puncture resistance of the double-glove hole puncture indication system manufactured by Molnlycke Health Care.³ Using a computerized needle penetration system, the computer plotted the vertical force exerted on the glove membrane by a wide diameter (0.45 mm) taper point needle. The penetration force data typically showed an initial penetration force followed by a maximum force. The initial force peak represents the first point at which the needle actually penetrated the glove membrane. The maximum force peak, however, was reached as the wider needle body followed the taper point through the channel created in the membrane. Penetration force data were collected for the Biogel® Indicator® Underglove, the standard Biogel® glove and a combination of the two into a Biogel® double-glove Puncture Indication System™. The initial and maximum penetration forces required for the needle to penetrate the Biogel® double-glove hole Puncture Indication System™ were significantly greater than those required to penetrate either the single Biogel® outer glove or the single Biogel® Indicator® Underglove.

Several clinical studies have been subsequently reported that confirm the value of the double-glove hole puncture indication system. In 1996, Brown⁴ reported on the use of this double-glove puncture indication system during trauma surgery. These double-glove puncture indication systems were used in 40 consecutive operative procedures for lower limb fracture fixation. Glove perforations were noted in

48% of the operative procedures. Perforations of the outer gloves were evident in 26 occasions; glove punctures of the undergloves were noted in two occasions. This clinical study indicated that there were no false-positive color changes. However, no indication of perforation was visible on one occasion. The study concluded that the rapidity and accuracy of color change allowed identification of glove punctures intraoperatively.

In the next year, Nicolai et al.⁵ described their experience with this glove system in major joint replacement surgery. They performed a prospective, randomized trial comparing the incidence of glove perforation using this new double-glove puncture Biogel® Indicator® system and standard double-gloves in total hip and knee replacement surgery. One or more perforations were detected in 14.6% of all double-glove systems. The investigators concluded that the new double-glove puncture indication system increased significantly the awareness of perforations. It was also observed that the dexterity of surgeons using the double-glove puncture Biogel® Indicator® system was similar to that of the standard double-gloves.

In 1999, Avery et al.⁶ evaluated this new double-glove puncture indicator system in maxillofacial trauma surgery. Surgeons wearing the double-glove puncture indication systems detected more perforations (79%) than surgeons wearing the standard double-gloves (19%). They noted that the accuracy of the double-glove puncture indication system was most noticeable in wet operating fields.

It is important to emphasize that for this system to be reliable, fluid must be present in the operative environment because ingress of fluid through the puncture hole is necessary to cause a color change in the double-glove hole puncture indication system. Consequently, this system is not reliable for surgeries that are performed in relatively dry clinical settings. The need for a wet surgical environment for this double-glove puncture indication system was clearly demonstrated in the evaluation of 50 consecutive patients in the emergency department.⁷ During wound closure, there was no color change in the double-glove puncture indication system indicating glove puncture. When the same gloves were then analyzed for holes by water filling and distention as described by Brough et al.,⁸ 14 of the 50 double-glove puncture indication systems failed. All 14 outer gloves were punctured, and three inner gloves had holes without demon-

strable injury to the skin. The results of this clinical study have caused one to alter the wound closure procedures in the emergency department. A sterile basin has been added to our sterile wound closure tray. When the tray is opened aseptically, sterile 0.9% sodium chloride is added to the sterile basin. The emergency physician then immerses his/her hands in the sterile fluid before beginning surgical wound treatment and periodically during longer surgeries. This glove exposure to fluid now allows the accurate detection of glove hole puncture using this double-glove puncture indication system.

When the Biogel® Reveal™ system was first developed, two pairs of gloves were packaged in the same heat-sealed paper overwrap. The inner glove, the green Biogel® Indicator® Underglove, was a half size larger than the outer Biogel® glove. This difference in the sizes of the underglove and the outer glove was based on the results of clinical trials reported by Webb and Pentlow.⁹ In their clinical studies involving ¹⁷ surgeons of all specialties, they reported that wearing the smaller glove on the outside of the larger glove was considered more comfortable than wearing a similarly sized underglove and outer glove. In addition, they found that double-gloving did not alter two-point discrimination or ability to tie surgical knots in their clinical study.

Clinical studies continue to be reported in the surgical literature demonstrating the merit of this unique latex double-glove puncture indication system. Aarnio and Laine¹⁰ confirmed the value of this double-glove puncture indication system in vascular surgery. The gloves used in this study were either double-gloves with the hole puncture indication system or the standard single glove used in the hospital. In 73 operations, 200 gloves were tested; half of them were double-gloves and half of them were single systems. Perforation was experienced in three double-glove systems. The perforation was detected in two of the three double-glove systems. Glove hole puncture was encountered in 12 of the single gloves. These investigators expanded their clinical evaluation of this double-glove hole puncture indication system to 885 operations.¹¹ According to their study, the early detection of glove hole perforations occurred in 86% of the perforations involving this double-glove hole puncture indication system.

Naver and Gottrup¹² investigated the incidence of glove perforations using this double-glove Indicator® system during various types of gastrointestinal

surgery. The surgeons, assistants and scrub nurses were assigned to wear either single gloves or the Biogel® Indicator® double-glove indication system; 566 pairs of gloves were tested. The perforation rate in single gloves was 17%; perforations were identified in both the outer Biogel® and the inner green Biogel® Indicator® gloves in only 2% of the double-gloves. In addition, they observed that double-gloving reduced the rate of blood contamination of the hands among surgeons from 13% using single gloves to 2% using double-gloves. The investigators concluded that the Biogel® Indicator® double-gloving system was recommended in gastrointestinal surgery because of the appreciable protection against blood contamination that it offers.

During operative procedures, the operating room personnel wear sterile surgical gloves that are designed to protect them and their patients against transmissible infections. The US Food and Drug Administration (FDA) has set compliance policy guides for manufacturers of gloves. The FDA allows surgeons' gloves whose leakage defect rates do not exceed 1.5% Acceptable Quality Level (AQL) to be used in operating rooms. The implications of this policy are potentially enormous to operating room personnel and the patient. For a surgeon with a transmissible infection using surgical gloves with this rate of leakage, it could be estimated that one in 40 of his/her patients could potentially become infected due to exposure via failure of his/her surgical gloves. This unacceptable risk to the patient could be significantly reduced by the use of sterile double surgical gloves.

Latex Allergy Among Operating Room Personnel

Operating room personnel have a high frequency of exposure to latex gloves which has led to the development of a greater than average incidence of latex allergies.¹³⁻¹⁴ In addition, they care for certain patient groups that are considered to be at risk for latex allergies. Staff allergic to latex and those caring for patients allergic to latex must wear latex-free gloves to protect themselves and their patients. In response to this latex allergy epidemic, Molnlycke Health Care has just developed a new non-latex double-glove hole puncture indication system.¹⁵

Because Molnlycke Health Care has devised non-latex double-glove hole puncture indication and latex double-glove Biogel® Indicator® puncture indication

systems, the accuracy of the blue non-latex double-glove hole puncture indication and the green latex double-glove Biogel® Indicator® systems has been evaluated in detecting holes made by five commonly used sterile Syneture™ (Covidien Incorporated, Mansfield, MA) surgical needles: taper point surgical needle, tapercut surgical needle, reverse cutting edge surgical needle, taper cardiopoint surgical needle and spatula surgical needle.¹³ After subjecting both the non-latex double-glove puncture indication system and the latex double-glove Biogel® Indicator® system to surgical needle puncture in each glove fingertip, these double-glove systems were immersed in a sterile basin of saline after which the double-gloved hands manipulated surgical instruments. Within two minutes, both the non-latex double-glove hole puncture indication system and the latex double-glove Biogel® Indicator® system accurately detected needle punctures in all of the surgical gloves, regardless of the dimensions of the surgical needles. In addition, the size of the color change visualized through the translucent outer glove did not correlate with needle diameter. On the basis of this extensive experimental evaluation, either the non-latex double-glove hole puncture indication system or the latex double-glove Biogel® Indicator® system should be used in all operative procedures by all operating room personnel.

The purpose of this study was to examine the reliability of these unique non-latex and latex double-glove hole puncture indication systems. These double-glove puncture indication systems were subjected to surgical needle puncture by a wide variety of surgical needles produced by one of the leading surgical needle manufacturers. The time of appearance of the color changes in the double-glove puncture indication system was carefully monitored. In addition, the intensity and configuration of the color changes following puncture by the different surgical needles were evaluated.

Molnlycke Health Care has designed an enhanced glove packaging system that offers features conducive to the medical industry's fast-paced environment, with improved accessibility through an easy-to-open film pack. This modified design offers easy access into a rectangular heat-sealed plastic overwrap. One side of the overwrap has product information printed on its surface; the other side is devoid of information, indicating that it is the back of the overwrap. One end of the overwrap has two unsealed edges that extend to its heat-sealed border. One unsealed edge from the

front of the overwrap has the directions “pull down to open.” With the unsealed edges grasped between the thumb and index fingertip of each hand, the glove package is opened to expose the paper wallet containing two surgical gloves.

The Biogel® Indicator® Underglove is a green latex glove that is used in combination with any other Biogel® latex surgical glove to create a double-glove puncture indication system. This underglove has a methacrylate polymer lining bonded to its inner surface that enables it to be donned on damp, wet or dry hands. The outer surface is specially treated so that the underglove can be easily donned by a latex outer glove. This methacrylate polymer lining allows donning without the presence of cornstarch powders, eliminating glove-powder complications. Its thickness at the fingertip is 0.19 mm. The glove has a curved finger design. The glove is manufactured to contain 50 µg or less of water extractable latex protein per gram. This underglove has a distinct green color that is not apparent when the underglove is covered by the translucent surface of the outer glove. When the outer glove is punctured, leakage of fluids through the puncture hole allows the green underglove to be visualized through the translucent outer glove.

In this study, the standard Biogel® or the Biogel® Super-Sensitive™ gloves were used as the outer gloves. These outer gloves have Biogel® coatings on only the inner surfaces of the gloves. These outer gloves are translucent, permitting visualization of color changes in the underglove in the event that these outer gloves are punctured. The standard Biogel® glove is a relatively thick glove with a micro-roughened surface. The thickness of its fingertip is 0.25 mm. It also contains 50 µg or less of water extractable latex protein per gram. In contrast, the Biogel® Super-Sensitive™ glove is approximately 20% thinner than the standard Biogel® glove, and its thickness at the fingertip is 0.19 mm.

In addition, Molnlycke Health Care has designed the first non-latex double-glove hole puncture indication system. The blue underglove, Biogel® Skinsense® N Universal has a polymer coating on its inner surface and a special treatment of its outer surface that allows it to be used either as a single glove or as part of a double-glove puncture indication system. Its thickness is remarkably similar to the green latex Biogel® Indicator® glove, measuring 0.20 mm. It has a distinct dark blue color that becomes apparent following glove puncture of the translucent light blue outer glove.

The non-latex outer glove, Biogel® Skinsense® PI, has a polymer coating on its inner surface. This non-latex glove, made of polyisoprene, has the same thickness (0.20 mm) as the non-latex underglove. This can either be donned over damp, wet or dry hands, or can serve as the outer glove of the non-latex double-glove hole puncture indicator system. Its translucent light blue color allows visualization of the dark blue underglove after puncture of this outer glove.

Postexposure Prophylaxis of Operating Room Personnel

For all operating room personnel, the potential exists for blood and body fluid exposure. This exposure places the operating room personnel at risk for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and human T-cell lymphotropic virus type I infection (HTLV-I).¹⁶⁻¹⁹ This exposure occurs either as a percutaneous injury (eg, a needlestick or cut with a sharp object), or contact with mucous membrane, or non-intact skin (eg, exposed skin that is chapped, abraded, or afflicted with dermatitis) or with blood, tissue, or other body fluids that are potentially infectious.^{16,17} The risk of infection from these viruses is extremely low even when operating room personnel come in contact with feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus, unless they contain blood. The purpose of this part of the continuing education program is to provide recommendations for operating room personnel and patients exposed to these bloodborne diseases. These recommendations include the following: (1) treatment of the exposure site, (2) evaluation of the type of exposure, (3) evaluation of the exposure source, (4) preparation of exposure report, and (5) postexposure prophylaxis for HBV, HCV, HIV and HTLV-I.

Treatment of the Exposure Site

During the last decade, there have been numerous technologic advances in wound care that have allowed the open wound to heal without infection. These technologic innovations have emerged from comprehensive, well-designed, experimental and clinical studies in microbiology, molecular biology, and mechanical engineering. These technologic advances in wound repair have gradually transformed the decision-making process in emergency wound care. The exposure

site must be examined using aseptic technique with mask and gloves. The surgeon should examine and repair the wound using the sterile powder-free double-gloves. Powdered surgical gloves should be avoided because the powder on surgical gloves causes damage to all tissues and is the vector for the latex allergy epidemic.²⁰ Ideally, the examiner should wear a sterile double-glove puncture indication system that has been developed for the accurate detection of a hole in the outer glove.²¹ It consists of a colored underglove within the translucent outer glove. When a hole in the outer glove occurs in the presence of fluids, the underglove develops a color change around the needle puncture hole, which is a visible indicator for immediate glove change. If hair removal around the wound is necessary to visualize accurately the exposure site, surgical clippers, rather than a razor, should be employed for atraumatic removal of the hair.²² The exposure site should be washed with a sterile fine pore-cell size sponge soaked in poloxamer 188 (ShurClens™, ConvaTec, Inc., Skillman, NJ).²³ Poloxamer 188 has been used to cleanse wounds in more than 10,000,000 patients without an adverse effect.

The commercially available surgical scrub solutions that contain iodophors or chlorhexidines are not safe for use in wounds.²⁴ These solutions contain toxic antiseptic agents and detergents that damage tissue defenses and potentiate the development of infection. The cleansed exposure site should then be covered by a sterile dressing.

Evaluation of the Type of Exposure

The type of exposure should be evaluated for its potential to transmit HBV, HCV, HIV and HTLV-I based on the type of body substance involved and the route and severity of exposure.²⁵ In most cases, there is evidence of compromised skin integrity which includes dermatitis, abrasion or open wound. Blood, fluid, fluid containing visible blood, or other potentially infectious fluid, including semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, or tissue, can be also infectious for transmission of bloodborne viruses. The routes for exposure to these fluids or tissue that pose a risk for bloodborne virus transmission is usually a percutaneous injury (ie, needle-stick or other penetrating sharps-related event) or through contact with a mucous membrane. For HCV and HIV, exposure to a blood-filled hollow

needle or visibly bloody instrument carries a higher risk than exposure to a needle that was used for giving an injection. Furthermore, any direct contact with a concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation.

Evaluation of the Exposure Source

The person whose blood or body fluid is the source of operating room personnel's exposure should be evaluated for HBV, HCV, HIV and HTLV-I infection. Information available in the patient's medical record at the time of exposure or from the source person might confirm or exclude bloodborne virus infection. The laboratory test results, admitting diagnosis, as well as previous medical history, must be reviewed carefully in the patient's hospital record. There are specific segments of the population that have increased risk for these bloodborne infections and, consequently, a higher prevalence of infection. These segments of the population have several important risk factors. Lifestyle risk factors include male homosexuality and injection drug use. Geographic risk factors involve infection acquired in economically disadvantaged parts of the world where the prevalence of bloodborne infections is higher. Occupational risk factors, such as healthcare workers exposed frequently to blood, are other important considerations.

If the HBV, HCV, HIV, and HTLV-I infection status of the source is unknown, the source person should be informed of the incident and tested for serologic evidence of bloodborne virus infection. When testing the source person, one must obtain informed consent in accordance with state and local laws. When the source person is found to be infected with any of these bloodborne viruses, he/she should be referred for appropriate counseling and treatment. Strict confidentiality of the source person must be maintained.

Testing for these bloodborne infections in the exposure source must be performed as soon as possible. Hospitals, clinics and other sites that manage operating room personnel exposed to bloodborne infections should consult their laboratories regarding the most appropriate test that will expedite obtaining the laboratory results. An FDA-approved rapid HIV antibody test kit is valuable in making the diagnosis, especially if testing by standard enzyme immunoassay (EIA) cannot be accomplished within 24-48 hours. A

new rapid test, Determine® (Abbott, Abbott Park, IL), detects HIV-1 and HIV-2 antibodies within 15 minutes by using 50 µL of serum or plasma.²⁶ It is important to point out that this rapid test detects HIV infection in serum from patients with CD4+ T-cell counts as low as 5 cells/mm³. Rapid testing is efficient for laboratories that have small volumes of fluid for testing, that require rapid results, and do not have technically advanced equipment, such as the EIA plate readers. Repeatedly reactive results by EIA or rapid HIV-antibody test are highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western Blot or immunofluorescent antibody is not necessary to initiate postexposure management, but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV should be confirmed by an additional test (ie, recombinant immunoblot assay (RIBATM) or HCV polymerase chain reaction (PCR)). Direct virus assays (eg, HIV p24 antigen EIA or test for HIV RNA or HCV RNA) for routine testing of HIV or HCV screening of source persons should not be instituted.

If the exposure is unknown or cannot be tested, information about where and under what circumstances the exposure occurred in the operating room should be assessed epidemiologically for the potential of transmission of HBV, HCV, HIV or HTLV-I. An important consideration in this decision is the prevalence of HBV, HCV, HIV or HTLV-I in the population group from which the contamination source is derived. For example, an exposure that occurs in a geographic area where injection drug use is frequent would be considered epidemiologically to have a higher risk of transmission than an exposure that occurs in a nursing home for the elderly. Testing of needles or other sharp instruments implicated in an exposure is not recommended. Healthcare providers should be aware of the state and local laws governing the collection and release of serostatus information on the source person following an occupational exposure.

If the source person is known to have an HIV infection, the following information should be gathered, including the person's stage of infection (ie, asymptomatic, symptomatic, or AIDS), CD4+ T-cell count, results of viral load testing, current and previous antiretroviral therapy and results of any genotypic or phenotypic viral resistance testing, so that

an appropriate postexposure prevention program can be instituted. If this information is not available, initiation of postexposure prophylaxis should not be delayed. Changes in the regimen can be made later. Reevaluation of the postexposure regimen should be done within 72 hours after exposure.

If the source person is HIV seronegative and has no clinical evidence of AIDS or symptoms of HIV infection, no further testing of the source person for HIV infection is indicated. The likelihood of the source person being in the "window period" of HIV infection in the absence of symptoms is rare.

Completion of Exposure Report

When an operating room exposure occurs, an occupational exposure report must be completed. This report should list the day and time of exposure. It should provide details of the procedure being performed, including where and how the exposure occurred. If the exposure was due to a sharp device, the type and brand of the device should be identified. In addition, the circumstances involved in the course of handling the device when the exposure occurred should be documented. Furthermore, the type and amount of fluid or material should be identified. In addition, the severity of the exposure should be carefully noted. For a percutaneous exposure, depth of injury and whether fluid was injected are important considerations. For a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin (eg, chapped, abraded, intact) should be listed. Moreover, the details of the exposure source should be carefully listed including whether the source material contained HBV, HCV, HIV or HTLV-I. If the source is HIV-infected, the stage of disease, history of antiretroviral therapy, viral load, and antiretroviral drug resistance must be identified. Pertinent information about the exposed person, to include hepatitis B vaccination and vaccine-response status, must be reported. This report should be completed with information about counseling, postexposure management and follow-up.

Postexposure Prophylaxis for HBV

The postexposure prophylaxis for HBV, HCV, HIV and HTLV-I differs considerably and will be discussed separately. HBV infection is a well-recognized risk for operating room personnel (Table 1).²⁵ The risk of

TABLE 1. Recommended postexposure prophylaxis for exposure to hepatitis B virus			
Vaccination and antibody response status of exposed workers ^a	<u>Treatment</u> Source HBsAg ^b positive	<u>Treatment</u> Source HBsAg ^c negative	<u>Treatment</u> Source unknown or not available for testing
Unvaccinated	HBIG ^d × 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated/known responder ^e	No treatment	No treatment	No treatment
Previously vaccinated/known nonresponder ^f	HBIG × 1 and initiate revaccination or HBIG × 2 ^g	No treatment	If known high risk source, treat as if source were HBsAg positive
Previously vaccinated/antibody response unknown	Test exposed person for anti-HBs ^h 1. If adequate ⁱ no treatment is necessary 2. If inadequate ^j administer HBIG × 1 and vaccine booster	No treatment	Test exposed person for anti-HBs ^h 1. If adequate ⁱ no treatment is necessary 2. If inadequate ^j administer vaccine booster and recheck titer in 1-2 months
a. Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.			
b. Hepatitis B surface antigen.			
c. Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.			
d. Hepatitis B vaccine.			
e. A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥ 10mIU/mL).			
f. A nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBs < 10mIU/mL).			
g. The option of giving one dose of HBIG and initiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.			
h. Antibody of HBsAg.			
i. Adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥ 10mIU/mL).			
j. Inadequate response to vaccination (i.e., serum anti-HBs < 10mIU/mL).			

HBV infection to operating room personnel is primarily related to the degree of contact with blood in the operating room and also to hepatitis B e antigen (HBeAg) status of the patient. In studies of health-care personnel who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis was 22% to 31% if the blood was both hepatitis B surface antigen (HBsAg) and HBeAg-positive. In these patients, the risk of developing serologic evidence of HBV infection was considerably greater, 37% to 62%. In contrast, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was only 1% to 6%. In these circumstances, the risk of developing serologic evidence of HBV infection was 23% to 37%.²⁵

All operating room personnel should be vaccinated against hepatitis B^{27,28} (Table 1). Prevacination serologic screening for previous infection is not recommended for persons being vaccinated because of occupational risk. Hepatitis B vaccine contains purified recombinant HBsAg and causes anti-HBs production to hepatitis B. Hepatitis B vaccines are licensed for preexposure and postexposure prophylaxis. Two recombinant DNA hepatitis B vaccines are available, one prepared by Merck Sharp and Dohme (Recombivax HB®) and the other by SmithKline Beecham (Engerix-B®). A genetically engineered yeast strain results in both vaccines. Recombivax HB® is available in 10 µg/mL of purified hepatitis B surface antigen, while Engerix-B® contains 20 µg/mL of the same antigen. A more concentrated solution of Recombivax® contains 40 µg/mL for use in patients who receive hemodialysis. Twinrix® (SmithKline Beecham) is a bivalent vaccine that produces protective antibodies against hepatitis A and hepatitis B.

As required under the National Childhood Vaccine Injury Act, all healthcare providers in the United States who administer any vaccine shall, prior to administration of the vaccine, provide a copy of the Vaccine Information Statements (VIS) (Fig. 1) produced by the CDC to the parent or legal representative of any child to whom the provider intends to administer such vaccine, or to any adult to whom the provider intends to administer such a vaccine. The VIS must be supplemented with visual presentation or oral explanations, as appropriate. If there is not a single VIS for a combination vaccine (eg, HAV/HBV), use the VIS for both HAV and HBV component vaccines. Copies of the VIS are available at [\[cines/pubs/vis/default.htm\]\(http://cines/pubs/vis/default.htm\), and are available in English as well as many other languages.](http://www.cdc.gov/vac-</p>
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The adverse reactions to the HBV vaccines are outlined to the patient or guardian in clear, understandable language. The VIS also emphasizes that in the rare event that you or your child has a serious reaction to a vaccine, a federal program (the National Vaccine Injury Compensation Program) has been created to help the individual pay for care required as a result of the adverse reaction. For details about the National Vaccine Injury Compensation Program, call (800) 338-2382, or visit www.hrsa.gov/bhpr/vicp.

Surveillance for vaccine-associated adverse events is an integral part of patient care in spite of the current record of safety of the HBV vaccine. Any adverse events suspected to be associated with HBV vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), (800) 822-7967. VAERS is a cooperative program for vaccine safety of the CDC and FDA. VAERS is a post marketing safety surveillance program that collects information about adverse events that occur after the administration of vaccines licensed in the United States. The website, vaers.hhs.gov, provides a nationwide mechanism by which adverse events following immunization may be reported, analyzed, and published. Also, the website provides a valuable vehicle for disseminating vaccine safety-related information to parents/guardians, healthcare providers, vaccine manufacturers, state vaccine programs, and other institutions and facilities.

The recommended schedule for hepatitis B vaccine is three doses administered at 0, 1 and 6 months. There is some evidence indicating the closer the last dose is given to 12 months after the first, the greater and longer lasting the antibody response will be. Interruption of the immunization schedule does not require that any dose be repeated, as long as the minimum intervals between doses are initiated. Vaccines produced by the different manufacturers can be used interchangeably despite the different doses. The dose used should be that recommended by the manufacturer. Hepatitis B vaccine must always be administered by the intramuscular route in the deltoid muscle with a needle 1 to 1.5 inches long.

Operating room personnel who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be evaluated 1 to 2 months after completion of the three-dose vaccination series for anti-HBs.²⁵ Operating room personnel

HEPATITIS B VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is hepatitis B?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus (HBV). HBV can cause:

Acute (short-term) illness. This can lead to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness is more common among adults. Children who become infected usually do not have acute illness.

Chronic (long-term) infection. Some people go on to develop chronic HBV infection. This can be very serious, and often leads to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are infected can spread HBV to others, even if they don't appear sick.

- In 2005, about 51,000 people became infected with hepatitis B.
- About 1.25 million people in the United States have chronic HBV infection.
- Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV.

Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by:

- contact with a mother's blood and body fluids at the time of birth;
- contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
- contact with objects that could have blood or body fluids on them such as toothbrushes or razors;
- having unprotected sex with an infected person;
- sharing needles when injecting drugs;
- being stuck with a used needle on the job.

2 Hepatitis B vaccine: Why get vaccinated?

Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of HBV infection, including liver cancer and cirrhosis.

Routine hepatitis B vaccination of U.S. children began in 1991. Since then, the reported incidence of acute hepatitis B among children and adolescents has dropped by more than 95% – and by 75% in all age groups.

Hepatitis B vaccine is made from a part of the hepatitis B virus. It cannot cause HBV infection.

Hepatitis B vaccine is usually given as **a series of 3 or 4 shots**. This vaccine series gives long-term protection from HBV infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- All children should get their first dose of hepatitis B vaccine **at birth** and should have completed the vaccine series by 6-18 months of age.
- Children and adolescents through 18 years of age who did not get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults **at risk for HBV infection** should be vaccinated. This includes:
 - sex partners of people infected with HBV,
 - men who have sex with men,
 - people who inject street drugs,
 - people with more than one sex partner,
 - people with chronic liver or kidney disease,
 - people with jobs that expose them to human blood,
 - household contacts of people infected with HBV,
 - residents and staff in institutions for the developmentally disabled,
 - kidney dialysis patients,

- people who travel to countries where hepatitis B is common,
- people with HIV infection.
- Anyone else who wants to be protected from HBV infection may be vaccinated.

4 Who should NOT get hepatitis B vaccine?

- Anyone with a life-threatening allergy to **baker's yeast**, or to **any other component of the vaccine**, should not get hepatitis B vaccine. Tell your provider if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a **previous dose of hepatitis B vaccine** should not get another dose.
- Anyone who is **moderately or severely ill** when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your provider can give you more information about these precautions.

Pregnant women who need protection from HBV infection may be vaccinated.

5 Hepatitis B vaccine risks

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The following **mild problems** have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, *could* cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic

reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit CDC websites at:
 - www.cdc.gov/ncidod/diseases/hepatitis
 - www.cdc.gov/vaccines
 - www.cdc.gov/travel



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

Vaccine Information Statement (Interim)
Hepatitis B (7/18/07) 42 U.S.C. § 300aa-26

Figure 1. Hepatitis B Vaccine Information Statement

who do not respond to the primary vaccine series should complete a second three-dose vaccine series or be evaluated to determine if they are HBsAg-positive. Revaccinated operating room personnel should be retested at the end of the second vaccine series. Persons who do not respond to the first three-dose vaccine series have a 30-50% chance of responding to a second three-dose series.²⁹

Operating room personnel who are found to be HBsAg-positive should be counseled on how to prevent HBV transmission to others and referred for further medical evaluation. Operating room personnel who do not respond to vaccination, and who are HBsAg-negative, should be susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection. It should be emphasized that these non-responders to vaccination need hepatitis B immune globulin (HBIG) prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood. Booster doses of hepatitis B vaccine are not recommended for these non-responders.

There are no reported risks to developing fetuses when hepatitis B vaccine is administered to pregnant women. While the vaccine contains non-infectious HBsAg particles, they should pose no risk to the fetus. Because HBV infection may result in severe disease for the mother and chronic infection for the newborn, neither pregnancy nor lactation should be considered a contraindication to vaccination of women. HBIG is also not contraindicated for pregnant or lactating women.²⁵

HBIG is prepared from pooled human plasma from selected donors with a high level of antibody to HBsAg (anti-HBs). The plasma from which HBIG is prepared is screened carefully for HBsAg and antibodies to HCV and HIV. During the process of preparation of HBIG, HIV is inactivated and eliminated from the final product. Since 1996, the final product is free of HCV RNA as recorded by PCR. All products since 1999 have been available in the United States using a manufacturing process that inactivates HCV and other viruses. There is no evidence that the commercially available HBIG has ever transmitted HBV, HCV, or HIV in the United States.³⁰

Serious adverse reactions from HBIG when administered as recommended have been rare. Local pain and tenderness at the injection site, urticaria, and angioedema might occur. Although rare, ana-

phylactic reactions have been reported following the injection of human immune globulin preparations.³¹ Consequently, persons with a history of anaphylactic reaction to immune globulin should not receive HBIG. There are many indications for administration of HBIG, including the following: percutaneous or mucosal exposure to blood containing hepatitis B virus, birth of an infant to a mother with acute hepatitis B infection, and sexual contact with an acute case of hepatitis B. If the exposure source is known to be positive, HBIG should be administered as soon as possible after exposure, preferably within 24 hours. The injection of HBIG should be at a site separate from the vaccine.

The efficacy of HBIG and/or hepatitis B vaccine has been examined in several prospective studies in various postexposure settings. For perinatal exposure to an HBsAg-, HBeAg-positive mother, a combination of HBIG and initiation of hepatitis B vaccine series at birth is 85 to 95% effective in preventing HBV infection.^{32,33} Regimens involving either multiple doses of HBIG alone or the hepatitis B vaccine series alone were 70 to 75% effective in preventing HBV infection.³⁴ Multiple doses of HBIG initiated within one week following percutaneous exposure to HbsAg-positive blood in the occupational setting provided an estimated 75% protection from HBV infection.³⁵⁻³⁸ The increased postexposure efficacy of the combination of HBIG and hepatitis B vaccine series in the perinatal setting, compared with HBIG alone, suggests that this combination therapy would prove superior in the occupational setting as well.

Hepatitis B vaccines are reported to be safe when administered to infants, children or adults.^{39,40} Approximately 100 million persons have received hepatitis B vaccine in the United States. The most common side effects from hepatitis B vaccination are mild to moderate fever as well as pain at the injection site. These side effects are reported no more frequently than among those receiving placebo.⁴¹ Surveillance of adverse events following hepatitis B vaccination in the United States has demonstrated no association between hepatitis B vaccine and the occurrence of serious adverse events, including Guillain-Barré syndrome, transverse myelitis, multiple sclerosis, optic neuritis, and seizures.⁴¹ While there have been several case reports that have claimed an association between hepatitis B vaccination and the demyelinating diseases, reviews by international

panels of experts have concluded that available data do not demonstrate a causal relationship between hepatitis B vaccination and demyelinating diseases, including multiple sclerosis.⁴²

Postexposure Prophylaxis for HCV

HCV is not transmitted efficiently through occupational exposures to blood. The average incidence of anti-HCV seroconversion after accidental percutaneous exposure from an HCV-positive source was 1.8%, varying from 0% to 7%.²⁵ One study noted that transmission occurred only from hollow-bore needles compared with other sharps.⁴³ No transmission in healthcare personnel has been reported from intact or non-intact skin exposures to blood. The high risk for HCV transmission in hemodialysis units has been contributed to poor infection control practices as well as environmental conditions of this hospital setting.^{44,45} In several studies, investigators have attempted to assess the effectiveness of immune globulin following hospital exposure to hepatitis C. These studies have been difficult to interpret because they lack uniformity in diagnostic criteria and study design.²⁶ In one experimental study, the investigators found no therapeutic merit in the use of high anti-HCV titer immune globulin administered to chimpanzees one hour after exposure to HCV-positive blood.⁴⁶ In 1994, the Advisory Committee on Immunization Practices (ACIP) concluded that using immune globulin for postexposure prophylaxis for hepatitis C was not indicated.⁴⁷

No clinical trials have been conducted to evaluate postexposure using antiviral agents (eg, interferon with or without ribavirin) to prevent HCV infections. Consequently, antiviral agents are not approved by the FDA for this indication. Clinical studies suggest that an established infection must be present before interferon can be an effective treatment. Kinetic studies indicate that the effect of interferon on chronic HCV infection occurs in two phases. During the first phase, interferon interrupts the production or release of virus from infected cells. In the second phase, virus is eliminated from infected cells.⁴⁸

In the absence of postexposure prophylaxis for HCV, recommendations for postexposure management are designed to achieve early identification of chronic disease and, if evident, referral for evaluation of treatment options. However, there is a theoretical argument that intervention with antivirals when HCV

RNA first become detectable might indeed prevent the development of chronic infection. Data from studies initiated in the United States indicated that a short course of interferon started early in the course of acute hepatitis C was associated with a higher rate of resolved infection than that achieved when therapy has begun after chronic hepatitis C had become well established.⁴⁹⁻⁵¹ It is important to emphasize that no studies have been initiated that have evaluated the treatment of acute infection without evidence of liver disease.

Hospitals must establish policies and procedures for testing operating room personnel for HCV after percutaneous or mucosal exposures to blood and insure that all personnel are familiar with these policies. The patient first must be tested for anti-HCV. For operating room personnel exposed to an HCV-positive patient, immediate baseline testing for anti-HCV and alanine aminotransferase (ALT) activity must be performed. If early diagnosis of HCV infection in the hospital personnel is desired, testing for HCV RNA must be initiated at 4 to 6 weeks. In any event, follow-up testing at 4 to 6 months for anti-HCV and ALT activity is mandatory. All anti-HCV results that are positive must be confirmed by enzyme immunoassay using supplemental anti-HCV testing (eg, recombinant immunoblot assay) RIBATM.¹⁸

Counseling Operating Room Personnel Exposed to Viral Hepatitis

Operating room personnel exposed to HBV- or HCV-infected blood do not need to take any special precautions to prevent transmission to other patients during the 4- to 6-month follow-up period.²⁵ However, they must refrain from donating blood, plasma, organs, tissue or semen. In addition, the exposed person does not need to modify sexual practices or refrain from becoming pregnant. The exposed person can continue breastfeeding.

No modifications in the operating room personnel's patient-care responsibilities are necessary to prevent transmission to their patients based solely on their exposure to HBV- or HCV-positive blood. However, if the exposed operating room personnel become acutely infected, the person should be evaluated. In 1991, the Centers for Disease Control made recommendations for preventing transmission of hepatitis B virus as well as HIV during exposure-prone invasive procedures.⁵² It has been reported that

the risk of HIV transmission to a healthcare worker after percutaneous exposure to HIV-infected blood was considerably lower than the risk of HBV transmission after percutaneous exposure to HBeAg-positive blood (0.3% versus approximately 30%).⁵³⁻⁵⁵ On this basis, it can be assumed that the risk of transmission of HIV from an infected healthcare worker to a patient during an invasive procedure will be proportionately lower than the risk of HBV transmission from a HBeAg-positive healthcare worker to a patient during the same procedure.

Since the introduction of serologic testing for HBV infection in the early 1970s, there have been published reports of more than 20 clusters in which a total of more than 300 patients were infected in association with treatment by a HBV-infected healthcare worker.⁵² Five clusters were linked to obstetricians or gynecologists, and three were linked to cardiovascular surgeons. In addition, recent reports strongly suggest HBV transmissions from three surgeons to patients in 1989 and 1990 during colorectal, abdominal and cardiothoracic surgery.⁵⁶

Seven of the healthcare workers who were linked to published clusters in the United States were allowed to perform invasive procedures following modification of invasive techniques (eg, double-gloving and restriction of certain high-risk procedures).⁵⁶⁻⁶³ For five healthcare workers, there was no further transmission. In two instances involving an obstetrician/gynecologist and an oral surgeon, HBV was transmitted to patients after techniques were modified.^{57,59}

Despite adherence to principles of universal precautions, certain invasive surgical and dental procedures have been implicated in the transmission of HBV from infected healthcare workers to patients. These procedures should be considered exposure-prone and include certain oral, cardiothoracic, colorectal, and obstetric/gynecologic procedures. Experience with HBV indicates that other invasive procedures would pose substantially lower risk, if any, of transmission of HIV and other bloodborne pathogens from an infected healthcare worker to patients.

The Centers for Disease Control has made the following recommendations for healthcare workers with either HIV, HBV or HCV infections²⁵:

1. All healthcare workers should adhere to universal precautions including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments.

2. Healthcare workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment and devices used in performing invasive procedures until the condition resolves.
3. Currently available data provide no basis for recommendations to restrict the practice of healthcare workers infected with HIV or HBV who perform invasive procedures not identified as exposure-prone.
4. Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.
5. Healthcare workers who perform exposure-prone procedures should know their HIV antibody status. Healthcare workers who perform exposure-prone procedures and do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status, and if that is positive, should also know their HBeAg status.
6. Healthcare workers who are infected with HIV or HBV should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and have been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the healthcare worker's seropositivity before the patient undergoes exposure-prone invasive procedures.
7. Mandatory testing of healthcare workers for HIV antibody, HBsAg or HBeAg was not recommended.
8. No recommendations exist regarding restricting the professional activities of healthcare workers with HCV infection.¹⁸

Postexposure Prophylaxis for HIV

In prospective studies of healthcare personnel, the average risk of HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be approximately 0.3%.⁵² After a mucous membrane exposure, the average risk of HIV infection is even lower, 0.09%. Although episodes of HIV transmission after non-intact skin exposure have been documented, the average risk for transmission

by this route has not been precisely quantified.⁶⁴ As of June 2000, the Centers for Disease Control has received reports of 56 U.S. healthcare personnel with documented HIV seroconversion associated with an occupational HIV exposure.⁶⁵ An additional 138 incidences of HIV infection in healthcare personnel are considered possible occupational HIV transmissions. In these latter cases, HIV conversion after a specific exposure was not documented.

Epidemiologic and laboratory studies indicate that several factors may influence the risk of HIV transmission after an occupational exposure. In a retrospective case-control study of healthcare personnel who had percutaneous exposure to HIV, the risk for HIV infection was reported to be increased with exposure to a larger quantity of blood from the source person as indicated by (1) a device visibly contaminated with the patient's blood, (2) a procedure that involved a needle being placed in a vein or artery, or (3) a deep injury.⁶⁶ The risk also was enhanced by exposure to blood from source persons with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of AIDS or other important factors (eg, the presence of syncytia-inducing strains of HIV). A laboratory study that demonstrated that more blood is transferred by deeper injuries and hollow-bore needles lends credence to the observed variation in risk related to blood quantity.⁶⁷

The use of the source person's viral load of HIV as a measure of viral titer for assessing transmission risk remains to be established. Plasma viral load (eg, HIV RNA) reflects only the level of cell-free virus in the peripheral blood; latently infected cells may transmit infection in the absence of viremia. Although a lower viral load (eg, <1,500 RNA copies/mL) or one that is below the limits of detection probably suggests a lower titer exposure, it does not eliminate the possibility of transmission.²⁵

Operating room personnel exposed to HIV should be evaluated within hours (rather than days) after exposure and should be tested for HIV at baseline to establish the infection status at the time of exposure. If the source person is seronegative for HIV, baseline testing or further follow-up of the exposed operating room personnel is not necessary. Serologic testing must be made available to all operating room personnel who are concerned that they might have been occupationally infected with HIV. When considering HIV postexposure prophylaxis, the evaluation should include information about

medications the operating room personnel might be taking and any current or overlying medical conditions or circumstances that might influence drug selection, to include pregnancy, breastfeeding, or renal or hepatic disease. Recommendations have been developed for the operating room personnel that have been exposed to a source person with HIV infection or when information suggest the likelihood that the source person is HIV-infected (Table 2 and Table 3). These recommendations are based on the risk of HIV infection after different types of exposure as well as on limited data regarding efficacy and toxicity of postexposure prophylaxis. Because most occupational HIV exposures fortunately do not result in the transmission of HIV, potential drug toxicity must be considered carefully when prescribing postexposure prophylaxis. To assist with the initial management of an HIV exposure, hospitals should have drugs for an initial postexposure prophylaxis regimen selected and available for use. Ideally, these recommendations should be implemented in consultation with physicians who have expertise in antiretroviral therapy and HIV transmission.

Timing and Duration of Postexposure Prophylaxis

Postexposure prophylaxis should be started as soon as possible. Animal studies have revealed the importance of starting postexposure prophylaxis for HIV soon after an exposure.⁶⁸⁻⁷⁰ When questions exist about which antiretroviral drugs to use or whether to use a basic or expanded regimen, begin the basic regimen immediately rather than delaying postexposure prophylaxis administration. Although animal studies indicate that postexposure prophylaxis is substantially less beneficial when started more than 24 to 36 hours postexposure, the interval after which no benefit is gained from postexposure prophylaxis for humans is not known. Consequently, postexposure prophylaxis should be initiated even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval, such as one week, might be considered for exposures that present an increased risk for transmission. Today, the optimal duration of postexposure prophylaxis for HIV is still not known. Because four weeks of zidovudine (ZDV) was reported to be protective in occupational and animal studies, postexposure prophylaxis should be administered for four weeks, if tolerated.^{66,71}

Table 2. Recommended HIV postexposure prophylaxis for percutaneous injuries				
Infection status of source				
Exposure Type	HIV-Positive Class 1 ¹	HIV-Positive Class 2 ²	Source of unknown HIV status ³	Unknown source ⁴
Less severe ⁵	Recommend basic 2-drug PEP ⁶	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ⁶ for source with HIV risk factors ⁷	Generally no PEP warranted; however, consider basic 2-drug PEP ⁶ in setting where exposure to HIV-infected persons is likely
More severe ⁸	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ⁶ for source with HIV risk factors ⁷	Generally no PEP warranted; however, consider basic 2-drug PEP ⁶ in setting where exposure to HIV-infected persons is likely
1. HIV-Positive, Class 1 – asymptomatic HIV infection or known low viral load (e.g., < 1,500 RNA copies/mL).				
2. HIV-Positive, Class 2 – symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.				
3. Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).				
4. Unknown source (e.g., a needle from a sharps disposal container).				
5. Less severe (e.g., solid needle and superficial injury).				
6. The designation "consider PEP" indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.				
7. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.				
8. More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).				

Table 3. Recommended HIV postexposure prophylaxis for mucous membrane exposures and nonintact skin¹ exposures

Infection status of source				
Exposure Type	HIV-Positive Class 1 ²	HIV-Positive Class 2 ³	Source of unknown HIV status ⁴	Unknown source ⁵
Small volume ⁶	Recommend basic 2-drug PEP ⁷	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ⁷ for source with HIV risk factors ⁸	Generally no PEP warranted; however, consider basic 2-drug PEP ⁷ in setting where exposure to HIV-infected persons is likely
Large volume ⁹	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ⁷ for source with HIV risk factors ⁸	Generally no PEP warranted; however, consider basic 2-drug PEP ⁷ in setting where exposure to HIV-infected persons is likely
1. For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound.)				
2. HIV-Positive, Class 1 – asymptomatic HIV infection or known low viral load (e.g., < 1,500 RNA copies/mL).				
3. HIV-Positive, Class 2 – symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.				
4. Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).				
5. Unknown source (e.g., a needle from a sharps disposal container).				
6. Small volume (e.g., a few drops).				
7. The designation "consider PEP" indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.				
8. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.				
9. Large Volume (i.e., major blood splash).				

Use of Postexposure Prophylaxis When Status of Source Person is Unknown

If the source person’s HIV infection status is not known at the time of exposure, use of postexposure prophylaxis should be made on a case-by-case basis,

after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source.²⁵ If these considerations suggest a possibility for HIV transmission, and HIV testing of the source is pending, initiate a two-drug postexposure prophylaxis regimen until laboratory results have

been obtained, after which the therapy can be modified or discontinued.

In any event, postexposure prophylaxis for HIV should be started as soon as possible after exposure. The exposed person must be reevaluated 72 hours postexposure, especially as additional information about the exposure or source person becomes available. Postexposure prophylaxis should continue for four weeks, if tolerated

Postexposure Prophylaxis for Pregnant Operating Room Personnel

If the exposed person is pregnant, the evaluation of risk of infection and the need for postexposure prophylaxis should be approached as with any other operating room personnel who has had an HIV exposure. However, the decision to use any antiretroviral drugs during pregnancy should involve discussions between the woman and her primary care physician regarding the potential benefits and risks to her and her fetus. Certain drugs must be avoided in pregnant women because of their teratogenic effects. Because teratogenic effects were observed in primate studies, efavirenz (EFV) is not recommended during pregnancy. Moreover, reports of fatal lactic acidosis in pregnant women treated with a combination of stavudine (d4T) and didanosine (ddl) have prompted warnings about use of these drugs during pregnancy. Because of the risk of hyperbilirubinemia in newborns, indinavir (IDV) should be avoided in pregnant women shortly before delivery.²⁵

Recommendations for the Selection of Drugs for HIV Postexposure Prophylaxis

The selection of a drug regimen for HIV postexposure prophylaxis will be determined by the potential risk for infection as well as the potential toxicity of the drug. Because the drugs used in postexposure prophylaxis for HIV are potentially toxic, their use is not justified for exposures that pose a negligible risk for transmission. In addition, there is insufficient evidence to support recommendations for a three-drug regimen for all HIV exposures. Consequently, two regimens are suggested: a basic two-drug regimen that should be appropriate for most HIV exposures and an expanded three-drug regimen that should be used for exposures that present an increased risk for transmission. These regimens should be implemented

in consultation with physicians who have expertise in antiretroviral treatment and HIV transmission. Most HIV exposures will require a two-drug regimen using two nucleoside analogues (eg, ZDV and lamivudine (3TC); or 3TC and d4T; or d4T and ddl). The addition of a third drug should be considered for exposures that present an increased risk for transmission. Selection of a postexposure prophylaxis regimen for HIV should consider the comparative risk represented by the exposure as well as information about the exposure source including history of and response to antiretroviral therapy based on clinical response to include CD4+ T-cell counts, viral load measurements, and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the postexposure prophylaxis regimen for HIV, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended. Expert consultation is obviously needed. If this information is not immediately available, initiation of the postexposure prophylaxis regimen, if indicated, should not be delayed. Changes in the regimen can be made after postexposure prophylaxis has been initiated. Reevaluation of the exposed person must be undertaken within 72 hours after exposure.

Follow-up of Operating Room Personnel Exposed to HIV

HIV testing with EIA should be used to monitor for seroconversion. The routine use of direct virus assays (eg, HIV p24 antigen EIA or test for HIV RNA) to detect infection in the exposed operating room personnel is not recommended.⁷² The high rate of false-positive test results using these tests could lead to unnecessary patient anxiety and treatment changes. Despite the ability of direct virus assays to detect HIV infection a few days earlier than EIA, the infrequency of occupational seroconversion and increased cost of these tests has prompted the Centers for Disease Control not to recommend their routine use in this setting. In addition, the Centers for Disease Control recommends HIV-antibody testing for at least six months postexposure. Moreover, HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome. The monitoring and management of postexposure prophylaxis toxicity for HIV treatment should be done by a specialist skilled in the management of HIV.

It is important to emphasize that there is considerable emotional turmoil of the operating room personnel exposed to HIV.⁷³⁻⁷⁵ The operating room personnel are given seemingly conflicting information on the postexposure prophylaxis. First, they are told that a low risk exists for HIV transmission and a four-week regimen of postexposure prophylaxis might be recommended. They are then asked to commit to significant behavioral measures to prevent sexual transmission, all of which influence their lives for several weeks to months. These behavioral measures include abstinence or use of condoms to prevent sexual transmission and to avoid pregnancy as well as to refrain from donating blood, plasma, organs, tissue, or semen. If an exposed woman is breastfeeding, discontinuation of breastfeeding is recommended, especially in high-risk exposures.

The patient care responsibilities of an exposed person do not need to be modified, based solely on an HIV exposure. If HIV seroconversion is detected, the person's patient care responsibilities should be evaluated according to published recommendations for infected healthcare personnel.⁷⁶ XIV. Postexposure Prophylaxis for HTLV-I/II The year 2004 marks the 24th anniversary of the discovery of the first human retrovirus, human T-cell lymphotropic virus-I (HTLV-I).⁷⁷ Its discovery has had several notable implications. First, this retrovirus provided clear proof of a relationship between viruses and cancer. Second, the obvious association of HTLV-I with a neurologic disease similar to multiple sclerosis created an opportunity to study the mechanisms that lead to chronic demyelinating diseases. Finally, its identification clearly facilitated the discovery and isolation of HIV, which has caused a global epidemic of a rapidly progressing fatal illness, AIDS. While the AIDS epidemic justifiably captured the attention of the most gifted scientists in the world, scientific attention to HTLV-I was dramatically diminished, permitting the development of a global epidemic of HTLV-I that causes fatal chronic diseases.

Another retrovirus, HTLV-II, has a biologic similarity to that of HTLV-I. Because of the absence of distinguishing serologic assays, HTLV-I and HTLV-II were often first grouped together in seroepidemiologic studies. When serologic assays were developed to distinguish these two retroviruses, it was realized that HTLV-II played a different role in the development of certain neurologic, hematologic, and dermatologic diseases.

The major modes of HTLV-I and HTLV-II transmission are perinatally (predominantly through breastfeeding), parenterally (through blood transfusions or exposure to needles and syringes contaminated with blood) and sexually. Promising public health initiatives to prevent HTLV-I and HTLV-II infection include routine screening of blood transfusion, protected sex, and avoidance of breastfeeding. Transmission by blood transfusions has been diminished by screening blood donors as is practiced in Japan, United States, France and certain islands of the West Indies.¹⁹ Despite the severe consequences of these bloodborne diseases, they have been ignored by the US healthcare profession. When asymptomatic carriers of HTLV-I or HTLV-II are identified by blood banks, this information will be kept confidential and not become part of the patient's medical record. The blood bank will not report the patient's condition to the blood donor's primary physician, the Health Department or the Centers for Disease Control.

The Centers for Disease Control wrote a position paper for counseling persons infected with HTLV-I and HTLV-II.⁷⁸ Its recommendations for counseling include the following: (1) share the information with their physician, (2) refrain from donating blood, semen, body organs or other tissues, (3) refrain from sharing needles or syringes with anyone, (4) refrain from breastfeeding infants, and (5) consider the use of latex condoms to prevent sexual transmission. Because this bloodborne disease is not reported to the state health departments, the Centers for Disease Control has no information regarding the incidence of these bloodborne infections in the United States. It has set no guidelines for postexposure prophylaxis of operating room personnel exposed to these bloodborne diseases. If the Centers for Disease Control does not mandate that it is a reportable infection, it will continue to be ignored by hospitals in the United States.

Occupational Exposure Management Resources

Operating room personnel who sustain an occupational injury that may expose them to a bloodborne disease may be either unfamiliar with the postexposure prophylaxis that they are receiving or dissatisfied with the clinical expertise of the physicians providing postexposure prophylaxis. In these cases, there are superb 24-hour resources staffed by personnel trained

in postexposure prophylaxis. The National Clinicians' Postexposure Prophylaxis Hotline (PEpline) is a unique resource for operating room personnel who have questions about postexposure prophylaxis. Its staff can be contacted by telephone, (888) 448-4911. This program is conducted by the University of California-San Francisco/San Francisco General Hospital staff. This program receives support from the Health Resources and Services Administration Ryan White CARE Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and Centers for Disease Control. It has a valuable internet website that contains updated information (www.ucsf.edu/hivcntr). This service has been expanded to include a hepatitis hotline. Its telephone number is (888) 443-7232, and it has a valuable website (<http://www.cdc.gov/hepatitis>). A website has also been developed to help clinicians manage and document occupational blood and body fluid exposures. It is developed and maintained by the University of California, Los Angeles (UCLA), Emergency Medicine Center, UCLA School of Medicine, and is funded in part by the Centers for Disease Control and the Agency for Healthcare Research and Quality. The success of these informational systems has led to their serving as models for dissemination of expert information regarding other emergencies, such as malignant hyperthermia. That information service is managed by the Malignant Hyperthermia Association of the United States, (607) 674-7901, www.mhaus.org.

References

1. Edlich RF, Wind TC, Hill LG, Thacker JG, McGregor W. Reducing accidental injuries during surgery. *J Long Term Eff Med Implants*. 2003; 13(1): 1-10.
2. Palmer JD, Rickett JWS. The mechanisms and risks of surgical glove perforation. *J Hosp Infect*. 1992; 22: 279-286.
3. Manson TT, Bromberg WG, Thacker JG, McGregor W, Morgan RF, Edlich RF. A new glove puncture detection system. *J Emerg Med*. 1995; 13:357-364.
4. Brown JN. Surgeon protection: early recognition of glove perforation using a green under glove. *J R Coll Surg Edinb*. 1996; 41:395-396.
5. Nicolai P, Aldam CH, Allen PW. Increased awareness of glove perforation in major joint replacement. A prospective, randomized study of Regent Biogel reveal gloves. *J Bone Joint Surg Br*. 1997; 79: 371-373.
6. Avery CM, Taylor J, Johnson PA. Double gloving and a system for identifying glove perforations in maxillofacial trauma surgery. *Br J Oral Maxillofac Surg*. 1999; 37:316-319.
7. Fischer MD, O'Keefe JS, Williams FM, Neal JG, Syverud SA, Edlich RF. Failure of a new double-glove hole detection system in the emergency department. *J Biomed Mater Res (Appl Biomater)*. 1999; 48:199-201.
8. Brough SJ, Hunt TN, Barrie WW. Surgical glove perforations. *Br J Surg*. 1988; 75:317.
9. Webb JM, Pentlow BD. Double gloving and surgical technique. *Ann R Coll Surg Engl*. 1993; 75: 291-292.
10. Aarnio P, Laine T. Glove perforation rate in vascular surgery - a comparison between single and double gloving. *Vasa*. 2001; 30:122-124.
11. Laine T, Aarnio P. How often does glove perforation occur in surgery? Comparison between single gloves and a double-gloving system. *Am J Surg*. 2001; 181:564-566.
12. Naver S, Gottrup F. Incidence of glove perforations in gastrointestinal surgery and the protective effect of double gloves: a prospective and randomized controlled study. *Eur J Surg*. 2000; 166:1-3.
13. Edlich RF, Wind TC, Heather CL, Thacker JG. Reliability and performance of innovative surgical double-glove hole puncture indication systems. *J Long Term Eff Med Implants*. 2003; 13(2):69-83.
14. Woods JA, Lambert S, Platts-Mills TAE, Drake DD, Edlich RF. Natural rubber latex allergy: spectrum, diagnostic approach, and therapy. *J Emerg Med*. 1997; 15:71-85.
15. Tanner J. Biogel Skinsense N: surgical glove management for latex allergies. *Br J Nurs*. 2001; 10:682-686.
16. Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. *MMWR*. 1987; 36(suppl no. 2S).
17. Centers for Disease Control. Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR*. 1988; 37:377-82, 387-8.
18. Centers for Disease Control. Recommendations for the prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR*. 1998; 47 (No. RR-19).
19. Centers for Disease Control. Recommendations for preventing transmission of infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus during invasive procedures. *MMWR*. 1986; 35:221-223.
20. Ruhl CM, Urbancic JH, Foresman PA, Cox MJ, Rodeheaver GT, Zura RD, Edlich RF. A new hazard of

- cornstarch, an absorbable dusting powder. *J Emerg Med.* 1994; 12:11-14.
21. Manson TT, Bromberg WG, Thacker JG, McGregor W, Morgan RF, Edlich RF. A new glove puncture detection system. *J Emerg Med.* 1995; 13:357-364.
 22. Alexander JW, Fischer JE, Boyajian M, Palmquist J, Morris MJ. The influence of hair-removal methods on wound infections. *Arch Surg.* 1983; 118:347-352.
 23. Bryant CA, Rodeheaver GT, Reem EM, Nichter LS, Kenney JG, Edlich RF. Search for a nontoxic surgical scrub solution for periorbital lacerations. *Ann Emerg Med.* 1984; 13:317-321.
 24. Custer J, Edlich RF, Prumak M, Madden J, Panek P, Wangenstein OH. Studies in the management of the contaminated wound. V. An assessment of the effectiveness of pHisoHex and Betadine surgical scrub solutions. *Am J Surg.* 1971; 121:572-575.
 25. Centers for Disease Control. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV and HIV and recommendations for postexposure prophylaxis. *MMWR.* 2001; 50(RR11):1-42.
 26. Palmer CJ, Dubon JM, Koenig E, Perez E, Ager A, Jayaweera D, Cuadrado RR, Rivera A, Rubido A, Palmer DA. Field evaluation of the Determine rapid human immunodeficiency virus diagnostic test in Honduras and the Dominican Republic. *J Clin Micro.* 1999; 37:3698-3700.
 27. Department of Labor Occupational Safety and Health Administration. 29 CFR Part 1910. 1030. Occupational exposure to bloodborne pathogens; final rule. *Federal Register.* 1991; 56:64004-182.
 28. Centers for Disease Control. Immunization of Health-Care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR.* 1997; 46 (No. R-18).
 29. Hadler SC, Francis DP, Maynard JE, Thompson SE, Judson FN, Echenberg DF, Ostrow DG, O'Malley PM, Penley KA, Altman NL, et al. Long-term immunogenicity and efficacy of hepatitis B vaccine in homosexual men. *N Engl J Med.* 1986; 315: 209-214.
 30. Centers for Disease Control. Safety of therapeutic immune globulin preparations with respect to transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus infection. *MMWR.* 1986; 35:231-233.
 31. Ellis EF, Henney CS. Adverse reactions following administration of human gamma globulin. *J Allergy.* 1969; 43:45-54.
 32. Beasley RP, Hwang L-Y, Lee GC-Y, Lan CC, Roan CH, Huang FY, Chen CL. Prevention of perinatally transmitted hepatitis B virus infections with hepatitis B immune globulin and hepatitis B vaccine. *Lancet.* 1983; 2:1099-1102.
 33. Stevens CE, Toy PT, Tong MJ, Taylor PE, Vyas GN, Nair PV, Gudavallim M, Krugman S. Perinatal hepatitis B virus transmission in the United States: prevention by passive-active immunization. *JAMA.* 1985; 253:1740-1745.
 34. Beasley RP, Hwang L-Y, Stevens CE, Lin CC, Hsieh FJ, Wang KY, Sun TS, Szmuness W. Efficacy of hepatitis B immune globulin for prevention of perinatal transmission of hepatitis B virus carrier state: final report of a randomized double-blind, placebo-controlled trial. *Hepatology.* 1983; 3:135-141.
 35. Grady GF, Lee VA, Prince AM, Gitnick GL, Fawaz KA, Vyas GN, Levitt MD, Senior JR, Galambos JT, Bynum TE, Singleton JW, Clowdus BF, Akdamar K, Aach RD, Winkelman EI, Schiff GM, Hersh T. Hepatitis B immune globulin for accidental exposures among medical personnel: final report of a multi-center controlled trial. *J Infect Dis.* 1978; 138: 625-638.
 36. Seeff LB, Zimmerman HJ, Wright EC, Finkelstein JD, Garcia-Pont P, Greenlee HB, Dietz AA, Leevy CM, Tamburro CH, Schiff ER, Schimmel EM, Zemel R, Zimmon DS, McCollum RW. A randomized double-blind control trial of the efficacy of immune serum globulin for the prevention of post-transfusion hepatitis: a Veterans Administration cooperative study. *Gastroenterology.* 1977; 72:111-121.
 37. Prince AM, Szmuness W, Mann MK, Vyas GN, Grady GF, Shapiro FL, Suki WN, Friedman EA, Stenzel KH. Hepatitis B "immune" globulin: effectiveness in prevention of dialysis-associated hepatitis. *N Engl J Med.* 1975; 293:1063-1067.
 38. Centers for Disease Control. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through Universal childhood vaccination: recommendations of the Immunizations Practices Advisory Committee (ACIP). *MMWR.* 1991; 40 (No. RR-13): 1-25.
 39. Greenberg DP. Pediatric experience with recombinant hepatitis B vaccines and relevant safety and immunogenicity studies. *Pediatr Infect Dis J.* 1993; 12:438-445.
 40. Szmuness W, Stevens CE, Harley EJ, Zang EA, Oleszko WR, William DC, Zadorovsky R, Morrison JM, Kellner A. Hepatitis B vaccine: demonstration of efficacy in a controlled clinical trial in a high-risk population in the United States. *N Engl J Med.* 1980; 303:833-841.
 41. Shaw FE Jr, Graham DJ, Guess HA, Milstien JB, Johnson JM, Schatz GC, Hadler SC, Kuritsky JN, Hiner EE, Bregman DJ, et al. Postmarketing surveil-

- lance for neurologic adverse events reported after hepatitis B vaccination: experience of the first three years. *Am J Epidemiol.* 1988; 127:337-352.
42. Halsey NA, Duclos P, Van Damme P, Margolis H. Hepatitis B vaccine and central nervous system demyelinating diseases. *Viral Hepatitis Prevention Board. Pediatr Infect Dis J.* 1999; 18:23-24.
 43. Puro V, Petrosillo N, Ippolito G. Italian Study Group on Occupational Risk of HIV and Other Bloodborne Infections. Risk of hepatitis C seroconversion after occupational exposure in health care workers. *Am J Infect Control.* 1995; 23:273-277.
 44. Hardy NM, Sandroni S, Danielson S, Wilson WJ. Antibody to hepatitis C virus increases with time on hemodialysis. *Clin Nephrol.* 1992; 38:44-48.
 45. Niu MT, Coleman PJ, Alter MJ. Multicenter study of hepatitis C virus infection in chronic hemodialysis patients and hemodialysis center staff members. *Am J Kidney Dis.* 1993; 22:568-573.
 46. Krawczynski K, Alter MJ, Tankersley DL, Beach M, Robertson BH, Lambert S, Kuo G, Spelbring JE, Meeks E, Sinha S, Carson DA. Effect of immune globulin on the prevention of experimental hepatitis C virus infection. *J Infect Dis.* 1996; 173: 822-828.
 47. Alter MJ. Occupational exposure to hepatitis C virus: a dilemma. *Infect Control Hosp Epidemiol.* 1994; 15:742-744.
 48. Peters M, Davis GL, Dooley JS, Hoofnagle JH. The interferon system in acute and chronic viral hepatitis. *Prog Liver Dis.* 1986; 8:453-467.
 49. Fried MW, Hoofnagle JH. Therapy for hepatitis C. *Semin Liver Dis.* 1995; 15:82-91.
 50. Vogel W, Graziadei I, Umlauf F, Datz C, Hackl F, Allinger S, Grunewald K, Patsch J. High-dose interferon-alpha2b treatment prevents chronicity in acute hepatitis C: a pilot study. *Dig Dis Sci.* 1996; 41(suppl 12):81S-85S.
 51. Quin JW. Interferon therapy for acute hepatitis C viral infection—a review by meta-analysis. *Aust N Z J Med.* 1997; 27:611-617.
 52. Bell DM. Occupational risk of human immunodeficiency virus infection in healthcare workers: an overview. *Am J Med.* 1997; 102(suppl 5b):9-15.
 53. Henderson DK, Fahey BJ, Willy M, Schmitt JM, Carey K, Koziol DE, Lane HC, Fedio J, Saah AJ. Risk for occupational transmission of human immunodeficiency virus type 1 (HIV-1) associated with clinical exposures: a prospective evaluation. *Ann Intern Med.* 1990; 113:740-746.
 54. Marcus R. Surveillance of health-care workers exposed to blood from patients infected with the human immunodeficiency virus. *N Engl J Med.* 1988; 319:1118-1123.
 55. Gerberding JL, Bryant-LeBlanc CE, Nelson K, Moss R, Osmond D, Chambers HF, Carlson JR, Drew WL, Levy JA, Sande MA. Risk of transmitting the human immunodeficiency virus, cytomegalovirus and hepatitis B virus to health care workers exposed to patients with AIDS and AIDS-related conditions. *J Infect Dis.* 1987; 156:1-8.
 56. Heptonstall J. Outbreaks of hepatitis B virus infection associated with infected surgical staff. *CDR (Lond Engl Rev).* 1991; 1(8):R85-5.
 57. Lettau LA, Smith JD, Williams D, Lundquist WD, F, Sykes RK, Hadler SE. Transmission of hepatitis B with resultant restriction of surgical practice. *JAMA.* 1986; 255:934-937.
 58. Rimland D, Parkin WE, Miller GB, Schrack WD. Hepatitis B outbreak traced to an oral surgeon. *N Engl J Med.* 1977; 296:953-958.
 59. Goodwin D, Fannin SL, McCracken BB. An oral-surgeon related hepatitis-B outbreak. *California Morbid.* 1976; 14.
 60. Hadler SC, Sorley DL, Acree KH, Webster HM, Schable CA, Francis DP, Maynard JE. An outbreak of hepatitis B in a dental practice. *Ann Intern Med.* 1981; 95:133-138.
 61. Goodman RA, Ahtone JL, Finton RJ. Hepatitis B transmission from dental personnel to patients: unfinished business (Editorial). *Ann Intern Med.* 1982; 96:119.
 62. Ahtone J, Goodman RA. Hepatitis B and dental personnel: transmission to patients and outbreak of hepatitis B in a dental practice. *JAMA.* 1986; 255:3260-3264.
 63. Carl M, Blakey DL, Francis DP, Maynard JE. Interruption of hepatitis B transmission by modification of a gynaecologist's surgical technique. *Lancet.* 1982; 1:731-733.
 64. Centers for Disease Control. Update: human immunodeficiency virus infection in health-care workers exposed to blood of infected patients. *MMWR.* 1987; 36:285-289.
 65. Centers for Disease Control. HIV/AIDS Surveillance Report. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control, 2000:24 (vol 12, no.1).
 66. Cardo DM, Culver DH, Ciesielski CA. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med.* 1997; 337:1485-1490.
 67. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. *J Infect Dis.* 1993; 168:1589-1592.
 68. McClure HM, Anderson DC, Ansari AA, Fultz PN, Klumpp SA, Schinazi RF. Non human primate mod-

- els for evaluation of AIDS therapy. In: AIDS: anti-HIV agents, therapies and vaccines. *Ann N Y Acad Sci.* 1990; 616:287-298.
69. Walther-Jallow L, Nilsson C, Soderlund J, ten Haaf P, Makitalo B, Biberfeld P, Böttiger P, Heeney J, Biberfeld G, Thorstensson R. Cross-protection against mucosal simian immunodeficiency virus (SIVsm) challenge in human immunodeficiency virus type II-vaccinated cynomolgus monkeys. *J Gen Virol.* 2001; 82(Pt 7):1601-1612.
 70. Martin LN, Murphey-Corb M, Soike KF, Davison-Fairburn B, Baskin GB. Effects of initiation of 3'-azido, 3'-deoxythymidine (zidovudine) treatment at different times after infection of rhesus monkeys with simian immunodeficiency virus. *J Infect Dis.* 1993; 168:825-835.
 71. Tsai CC, Emau P, Follis KE, Beck TW, Benveniste RE, Bischofberger N, Lifson JD, Morton WR. Effectiveness of postinoculation (R)-9-(2-phosphorylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIV_{mac} infection depends critically on timing of initiation and duration of treatment. *J Virol.* 1998; 72: 4265-4273.
 72. Busch MP, Satten GA. Time course of viremia and antibody seroconversion following human immunodeficiency virus exposure. *Am J Med.* 1997; 102(suppl 5B):117-124.
 73. Gerberding JL, Henderson DK. Management of occupational exposures to bloodborne pathogens: hepatitis B virus, hepatitis C virus and human immunodeficiency virus. *Clin Infect Dis.* 1992; 14: 1179-1185.
 74. Armstrong K, Gorden R, Santorella G. Occupational exposure of health care workers (HCWs) to human immunodeficiency virus (HIV): stress reactions and counseling interventions. *Soc Work Health Care.* 1995; 21:61-80.
 75. Henry K, Campbell S, Jackson B, Balfour H Jr, Rhame F, Sannerud K, Pollack S, Sninski J, Kow S. Long-term follow-up of health care workers with work-site exposure to human immunodeficiency virus (Letter). *JAMA.* 1990; 263:1765.
 76. AIDS/TB Committee of the Society for Healthcare Epidemiology of America. Management of health-care workers infected with hepatitis B virus, hepatitis C virus, human immunodeficiency virus or other bloodborne pathogens. *Infect Control Hosp Epidemiol.* 1997; 18:349-363.
 77. Edlich RF, Arnette JA, Williams FM. Global epidemic of human T-cell lymphotropic virus type-I (HTLV-I). *J Emerg Med.* 2000; 18:109-119.
 78. Centers for Disease Control. Recommendations for counseling persons infected with human T-lymphotropic virus, types I and II. *MMWR.* 1993; 42(RR-9):1-13.

Reducing Accidental Injuries During Surgery

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All surgical healthcare professionals and their patients should be aware of exposure to blood from individuals infected with potentially transmissible disease. The site that was most susceptible to sharp injuries was the index finger of the surgeon's hand. It is also important to note that needles cause the vast majority of sharp injuries. During the last two decades, there have been two revolutionary advances in preventing accidental needlestick injuries during surgery that include the development of blunt tapering point needles as well as the double-glove hole indication systems. During the innovative development of blunt taper point needles, a glove manufacturer, Molnlycke, Inc., devised non-latex and latex double-glove hole puncture indication systems that are being used throughout the world. The reliability of these double-glove hole indication systems in detecting holes in the outer glove has been reliably documented by scientific studies that are published in peer-reviewed journals. On the basis of these extensive quantitative studies, the authors recommended that the double-glove hole indication system be used in all operative procedures to prevent the transmission of deadly bloodborne viral infections.

KEY WORDS: surgical accidental injuries, needle puncture, blunt taper point needles, double-glove hole indication systems

Introduction

All surgical healthcare professionals and their patients should be aware of exposure to blood from individuals infected with potentially transmissible disease. The danger to the patient was graphically illustrated in a report by Carl et al. in 1982.¹ Between January 1979 and January 1980, hepatitis B developed in three women within six months of gynecological surgery at a community hospital in Mississippi. An investigation of these hospital-acquired infections uncovered one other case of hepatitis B following gynecological surgery. The gynecologist who performed all four procedures was later found to be a chronic carrier of hepatitis B. Hepatitis B surface antigen subtyping on serum from this gynecologist and one of the hepatitis B patients gave identical results.

When the gynecologist was interviewed about his surgical technique, it was learned that he often held a surgical needle in his hand during suturing instead of using a needle holder. In addition, he remembered finding blood on his hands after removing his gloves at the end of surgical procedures several times during the year. The Mississippi State Health Department allowed the gynecologist "to resume his surgical practice after he agreed to use a needle holder during suturing and to wear two pairs of gloves during surgery. He also agreed to change gloves and surgical instruments if he pricked himself with a needle or other instrument or if he tore his glove." In addition, each of his subsequent patients were required to give written informed consent indicating that she knew her gynecologist had transmitted hepatitis B and that it was possible that he could do so again. No further transmission of hepatitis B was found after the gynecologist began wearing two pairs of gloves. The Mississippi State Health Department concluded that modifying the gynecologist's surgical technique by his wearing double-gloves was a far better solution to the problem of transmitting further disease than his dismissal or cessation of his practice.

Because operating room personnel are at highest risk among healthcare professionals for occupational hepatitis B and C infections due to their frequent exposure to blood, they are also at comparatively high risk for human immunodeficiency virus (HIV) infection.² McKinney and Young described a mathematical model for assessing the individual risk for HIV infection after multiple potential exposures over many years for surgeons and other operating room

personnel.³ They considered the risk to surgeons in three large hospitals with high, intermediate, and low estimated seroprevalence of HIV infection. They estimated the cumulative risk for a surgeon during a 30-year career using seroprevalence data from the three patient populations. In addition, they calculated the cumulative risk of HIV infection to surgeons by the rate of skin/glove puncture per procedure. They demonstrated that the combination of high skin puncture rate and high patient seroprevalence over a long period of time places the surgeon at considerable risk of HIV infection. If the seroprevalence rate of the hospital was 1% and the surgeon performed procedures with an estimated 10% skin puncture rate, the surgeon's cumulative risk of developing HIV infection after performing a total of 10,000 cases was 4%. When the seroprevalence rate of the hospital was 10% and the skin puncture rate was 10%, the surgeon's cumulative risk of developing HIV infection was calculated to be a staggering 33%. While these investigators acknowledged several limitations of their mathematical model, the results of their studies should be taken very seriously by operating room personnel.

In addition, these investigators suggested several options that would reduce the surgeon's susceptibility to HIV infection. First, surgeons could lower their risk by moving to a hospital or geographical region with a lower patient seroprevalence of HIV infection. Such a move would have serious personal and financial repercussions. Another suggested alternative was to reduce selectively the number of invasive procedures performed on patients with HIV infections. Obviously, this second alternative has serious medicolegal consequences. The third and most attractive alternative presented was to make a determined effort to decrease the likelihood of percutaneous exposures to blood during each surgical procedure.

Search for the Causes of Accidental Injuries During Surgery

Until the last decade, the development of strategies to prevent exposure of operating room personnel to blood has been limited by a lack of knowledge about the specific mechanisms of exposure. In 1988, Husain et al. reported results of a survey that was designed to determine the incidence of accidental injuries to surgeons during operations, the mechanism of injury, and the anatomic site on the surgeon's body.⁴

Factors such as duration of operations, time of day, and experience of surgeons were correlated to the frequency of injury. This survey included eight general surgeons, four orthopedic surgeons, two urologists, and four surgical residents in a hospital in Saudi Arabia. In their study of 2016 operations, the authors identified 112 accidental injuries (5.6%). Needlestick injuries accounted for the vast majority of injuries, 107 (95.5%). Only four (3.6%) were caused by cuts with surgical knives. One injury was caused by a burn from electrosurgery. The general surgeons and their residents in general surgery had the highest frequency of accidental injuries (7.0%), followed by the urologists (3%), and then the orthopedic surgeons (2.8%).

The site that was most susceptible to injury was the left index finger of the surgeon's hand, which represented 42 injuries (37.5%). Most injuries occurred during wound closure (85 injuries, 75.9%). Most needlestick injuries were noted as the needle emerged from the patient's tissue, puncturing the glove of the overlying finger that was not under direct vision of the surgeon. Longer operative procedures had a greater frequency of accidental injuries than did shorter operative procedures.

It was surprising that most injuries were considered trivial and disregarded completely (84 injuries, 75%). The surgeons changed their gloves in only 28 incidences (25%), rescrubbed their hands in 14 incidences (12.5%), and applied an antiseptic agent to the site of the injury in 13 incidences (11.6%).

In another effort to classify the mechanisms of accidental injuries in the operating room, Wright et al. had a nurse interview operating room personnel in a tertiary care teaching hospital immediately after glove tear or sharp injury.⁵ Potential exposures were categorized into the following three types: glove tears, sharp injuries, or gown leaks. A glove tear was considered to be any perforation of a glove that exposed bare skin. A sharp injury was judged to be an injury by a sharp instrument that caused pain to the injured person. A gown leak was judged to be any contact with body fluids at, or proximal to, the gown-glove margin. In the 2292 surgical operations within the scope of the study, most of the accidental operative exposures were glove tears (249, 75%). Sharp injuries accounted for 70 (21%). Gown leaks accounted for only 12 exposures.

Almost all of the glove tears were located over the digits (208, 84%). It was surprising that the mechanism of glove tears could not be identified

in the majority (168, 67%) of the 249 tears. More important, contact with the patient's blood was even more common when the mechanism of tear was not identified (128, 76%). It is important to note that the vast majority (92%) of the operating room personnel who experienced glove tears wore single gloves.

It is also important to note that needles caused the vast majority of sharp injuries (47, 67%). Only seven (10%) of the sharp injuries were from scalpels. The remaining 16 (23%) sharp injuries were from other instruments, such as the tip of the electrosurgical device, wire, skin staple, bone cutter, capillary tube, or chisel. Bleeding was caused by the injury in 56 (80%) cases of sharp injuries. The anatomic locations of sharp injuries were remarkably similar to those of glove tears. Eleven of the 12 gown leaks were encountered during gynecologic or general surgical abdominal operations. In either case, the surgeon or assistant was reaching into the abdomen filled with blood or fluid. One gown leak was noted when blood soaked through the gown cuff of a plastic surgeon.

The mechanism of exposure was recognized in 81 glove tears and 71 sharp injuries. In 34 exposures, the injured hand was being used as a retractor. The injured hand was suturing in 17 of these 34 exposures, and was usually passing the surgical needle through the patient's tissue at the time of injury.

In the 23 exposures identified as "hand holding an instrument," the injured hand was stationary over the wound and holding an instrument, while sharp instruments were passed into or out of the held instrument. Six exposures were encountered during hand tying of sutures, in which the suture material cut through the glove. In three of these incidents, the suture cut through the skin of the operating room personnel. When suture tying cut through the glove, the personnel were wearing single gloves.

On the basis of this comprehensive study, the investigators recommended preventive strategies to reduce the risk of exposure. First, the gloved hand should never be used as a retractor. Injuries to the hand holding a retractor could be reduced by distancing the hand from the site of such injuries by using longer forceps, by holding the forceps at a more acute angle with the skin, or by designing new forceps. Injuries from sharps not being used may be decreased by eliminating or shielding the sharp instrument. It was surprising to us that the investigators did not recommend double-gloves in all operative procedures.

In 1992, Tokars et al. reported the results of a multicenter observational study to record detailed information on the frequency and circumstances of blood contacts during surgical procedures.⁶ Observers, nurses, or operating room technicians were present at 1382 surgical procedures to record information about the procedure, the personnel present, and the percutaneous injuries that evolved. The investigators defined percutaneous injury as penetration of a healthcare worker's skin by a needle, other sharp instrument, or object that has been contaminated with a patient's blood. They judged recontact to be (1) contact of a sharp object with a patient's open wound after penetration of the healthcare worker's skin, or (2) injury of a worker by a bone fragment or surgical wire attached to the patient's body.

During the 1382 procedures observed in this study, 99 percutaneous injuries were noted. One or more injuries were recorded during the 95 procedures. As expected, suture needles accounted for the majority (76, 77%). Electrosurgical devices, scalpels, or wire caused only three injuries. Suture threads produced two injuries. There were single reports of injuries caused by a bone fragment, a bone hook, an orthopedic pin, a cannula, a retractor, scissors, a staple gun, and a trocar. The objects causing four injuries were not known. Suture needles placed on the surgical field that were not being used by the surgeon produced two injuries. As expected, injuries were more common on the non-dominant than on the dominant hand (63% vs. 34%). The most commonly injured area was the palmer surface of the distal forefinger.

We were alarmed by the operating room personnel's inappropriate responses to these percutaneous injuries. No glove changes were made after 15 injuries (15%). One individual (1%) placed a clean glove over the punctured glove. One individual was not wearing gloves at the time of injury. Immediate glove change was encountered in 61 (62%) of the injured operating room personnel. In 11 (11%) injuries, glove change was delayed from 5 to 15 minutes. Worker injury rates were greatest for surgeons and their resident staff (88 injuries). There were a total of 28 injuries to surgeons in which the sharp object that caused the injury recontacted the patient. The risk of injury, adjusted by confounding variables by logistic regression, was greatest during vaginal hysterectomy and lower during certain orthopedic procedures than during the other observed operative procedures.

Revolutionary Advances in Preventing Accidental Surgical Needlestick Injuries

During the last two decades, there have been two revolutionary advances in preventing accidental needlestick injuries during surgery that include the development of blunt tapering point needles as well as the double-glove hole indication systems.

Blunt Taper Point Needle

In 1991, Montz et al. announced the development of a blunt tapering point needle, with a dolphin-shaped tip that allows tissue penetration with minimum force, but does not puncture gloves.⁷ The surgeons used these needles in fascia closure. While they found that these needles were easily passed through the fascia, they did not penetrate the glove, limiting penetrating cutaneous injury to the surgeon and operating staff.

In 1993, Wright et al. expanded the evaluation of this new taper point needle.⁸ They compared the performance of the new blunt taper point needle with the traditional taper point needle in a prospective randomized trial of 69 patients who underwent total hip arthroplasty or hemi-arthroplasty. The surgeons wore two pairs of gloves. The outer pair was changed before the insertion of the prosthetic components and also before wound closure. The inner gloves were worn throughout the operation unless there was evidence of a glove puncture. After the operation, all gloves used by the surgeons were labeled and tested for perforations using water inflation as described by Brough et al.⁹ Each glove was inflated with water to a diameter of 10 cm above the palm and then squeezed to inflate each digit to a diameter of 4 cm, allowing the number and site of perforations to be identified.

The blunt taper point needle was used in 38 operations, while the standard taper point needle was employed in 31. At least one glove perforation was noted in 46 of the 69 operations (67%). A total of 138 outer gloves were worn during wound closure. When 62 outer gloves were worn using the standard taper point needle, 31 perforations were identified in 16 gloves. In the 76 outer gloves worn while using the blunt taper point needle, there were 18 perforations in 10 gloves. This reduced level of outer glove perforations encountered with the blunt taper point needle was statistically significant ($P = 0.049$). It is important to point out that the frequency of perforation of the

undergloves was not altered by needle configuration. Two undergloves were punctured by the blunt taper point needle at a site corresponding to the holes in the outer gloves. Similarly, two undergloves were punctured by standard taper point needles at sites corresponding to holes in the outer gloves.

It was significant that the undergloves were not changed during the operations. Moreover, it was uncertain at which stage the perforations had occurred. The surgeons rarely recognized glove damage, identifying it in only 11 cases (7%) of the perforations. The difficulty in detecting glove damage emphasizes the need for a glove hole puncture detection system that accurately identifies glove perforations.

In 1994, Miller and Sabharwal reported that the new blunt taper point needles could be effectively used for subcuticular skin closure.¹⁰ In 108 skin incisions in 40 patients, it was reported that the new blunt taper point needle successfully penetrated the subcuticular layers, allowing the use of a subcuticular closure technique with a reduced risk of glove puncture.

In 1994, Dauleh et al. evaluated the performance of blunt-tipped needles produced in their hospital workshops.¹¹ The tips of taper point and reverse cutting edge needles were subjected to this blunting process. When the standard needles were used in 253 procedures, 48 (18.9%) glove hole punctures were detected. In 22 of these cases, the needle penetrated the surgeon's skin. When blunt-tipped needles were used in 78 operations, only 2 glove perforations were identified, with no skin injury. The surgeons concluded that their blunt-tipped needles were a practical option against the hazard of needlestick injury. In a report from the Centers for Disease Control and Prevention (CDC) published in 1995, Bell et al. recommended the use of instruments, such as the new blunt taper point needle, new surgical protective equipment, and techniques that would reduce the likelihood of intra-operative blood exposure without adversely affecting patient care.¹²

Lewis et al. wrote a collective review on techniques to minimize sharp injuries in gynecologic and obstetric operations in 1995.¹³ They concluded that gynecologic surgery appears to have one of the highest rates of injury of the surgical specialties, and rates of injury vary by procedure within a given specialty. They also concluded that suture needles caused the majority of injuries. They reported that certain actions, such as holding tissue while suturing or cutting, were associated with a higher risk of injury.

In 1996, Hartley et al. reported a randomized trial of the new blunt taper point needle during mass closure of abdominal wounds.¹⁴ A total of 85 patients were randomly assigned to the clinical trial. The new blunt taper point needle was used in 46 patients, while 39 patients were subjected to wound closure with the standard taper point needle. Glove perforation was encountered in only 3 of the 46 abdominal wound closures accomplished with the blunt taper point needle. In contrast, 14 of the 39 operations using the standard taper point resulted in glove puncture. The surgeon was aware of the glove punctured by the standard taper point needle in 8 of the 14 incidences. The surgeon recognized 1 of the 3 punctures caused by the blunt taper point needle. In this study, none of the glove punctures led to needlestick injuries to the surgeons.

In 1996, Mingoli et al. evaluated the performance of another blunt taper point needle.¹⁵ The blunt needle and the standard tapered needle were subjected to a random number allocation in 200 patients. These needles were used for abdominal fascia closure in emergency general, vascular, and trauma procedures. The investigators reported that surgeons had 14 needlestick injuries and 76 perforations in 69 pairs of gloves. They reported that the standard taper point needles were responsible for all injuries and 58 (76%) glove perforations. The investigators concluded that the risk of glove perforations was 17-fold greater if standard taper point needles were used. They agreed that blunt needles reduced sharp injuries and improved safety for surgeons.

In 1997, the CDC reported their evaluation of blunt surgical needles in preventing percutaneous injuries among healthcare workers during gynecologic surgical procedures.¹⁶ The blunt point needles were evaluated as a potential replacement for conventional taper point needles in gynecologic surgery. From March 1993 through June 1994, trained nurse observers systematically recorded information about the nature and frequency of all percutaneous injuries and the number and type of suture needles used. They reported that 87 percutaneous injuries occurred during 84 (6%) of the 1464 procedures. Of the 61 injuries involving suture needles, none were encountered with the blunt taper point needle. The CDC concluded that the findings of this report support the use of blunt needles as an effective component of a percutaneous injury prevention program in gynecologic surgery and possibly for other surgical specialties.

Double-Glove Hole Indication Systems

In 1998, Berridge et al. reported a randomized controlled trial of vascular surgical operations in which the value of double-gloving was evaluated.¹⁷ Whenever possible, the blunt taper point needles were used. The frequency of perforations in the single and double-glove systems was determined by testing under high pressure of water. All episodes of obvious blood contamination of the hands or undergloves were determined. It was interesting to note that the frequency of perforation was greatest with double-gloves. However, the incidence of contamination was lowest with double-gloves. Contamination was judged to be present if there was macroscopic evidence of blood on the hand. For the 129 operating room personnel wearing single gloves, 18 had evidence of perforation. Beneath these 18 glove perforations, 8 had evidence of contamination. In contrast, 32 perforations were evident in the double-glove systems, but only 4 had evidence of contamination.

During the innovative development of the blunt taper point needles, a glove manufacturer (Molnlycke, Inc., Norcross, GA) devised non-latex and latex double-glove hole puncture indication systems. These double-glove systems accurately identify the site of glove hole puncture. In 2003, Edlich et al. conducted a biomechanical performance study that quantified the resistance to glove puncture of these double-glove hole puncture indication systems to blunt-tipped and standard taper point needles.¹⁸ The manufacturer of these surgical needles was Syneture™, Covidien, Inc. (Norwalk, CT).

The Biogel® Indicator® latex surgical underglove, made by Molnlycke, Inc., is a sterile green underglove that is used in combination with any other Biogel®-brand latex surgical glove to form a double-glove hole puncture indication system. This underglove has a polymer coating on its inner surface that allows it to be donned on damp, wet, or dry hands. Its outer surface is specially treated so that a latex outer glove can be easily donned over the underglove. The thickness of the fingertips of the undergloves is 0.19 mm. This underglove has a curved finger design and a distinct green color that becomes apparent when the outer translucent latex glove is punctured in the presence of fluid.

In this study, the sterile Biogel® or the Biogel® Super-Sensitive™ gloves have been used as the outer gloves.¹⁸ These outer gloves have polymer coatings on the inner surfaces of the gloves. They are trans-

lucent, permitting visualization of color changes in the underglove when the outer glove is punctured in the presence of fluid. The Biogel® glove is a relatively thick glove with a microroughened surface. The thickness of its fingertip is 0.25 mm. In contrast, the Biogel® Super-Sensitive™ glove is approximately 20% thinner than the standard Biogel® glove, with a fingertip thickness of 0.19 mm.

Molnlycke has recently designed the first non-latex double-glove hole puncture indication system. The underglove, Biogel® Skinsense® N Universal, has a polymer coating on its inner surface and a special treatment of its outer surface that allows it to be used as part of a double-glove hole puncture indication system. The thickness of this non-latex glove, made of Neoprene™, is remarkably similar to that of the latex Indicator® underglove, measuring 0.20 mm. It has a distinct dark blue color that becomes apparent when the translucent outer glove is punctured in the presence of fluid.

The non-latex outer glove, Biogel® Skinsense® Polyisoprene, has a polymer coating on its inner surface. This non-latex glove, made of polyisoprene, has the same thickness (0.20 mm) as the non-latex underglove. It can be donned with damp, wet, or dry hands or can serve as the outer glove of the non-latex double-glove hole puncture indication system. After outer glove puncture, its translucent light blue color allows visualization of the dark blue underglove in the presence of fluid.

This technique for measuring glove puncture resistance simulates the standard test for material resistance to puncture outlined by the American Society for Testing and Materials (West Conshohocken, PA).¹⁹ Measurement of puncture resistance was accomplished using a stationary support assembly affixed to the lower arm of a tension testing machine. Three curved needles, produced by Syneture™, were used in this evaluation: taper point needle, blunt taper point needle, and blunt-point needle. The taper point needle tapers to a sharp point. In contrast, the blunt taper point needle has a remarkably similar geometry to the taper point needle, except that its point has a blunt ending at the tip of the needle. The geometry of the blunt-point needle differs from those of the taper point and blunt taper point needles. Instead of tapering to either a sharp or dull tip, it has no taper at all. The full needle diameter extends to the tip of the needle, which has a blunt configuration. Each surgical needle was firmly mounted into a suitable fixture

and attached to a penetrometer stand. The order in which the needles were tested was randomly assigned. The whole assembly was attached to the compression load cell of an Instron model 1222 (Instron Corp., Canton, MA). The glove membrane was supported between two flat metal plates. The glove membrane or membranes were affixed to the top plate, which was shaped like a ring and served to secure the edges of the sample. The top plate, with the attached glove membrane or membranes, was then placed over another plate containing 24 holes whose size was 0.6 cm diameter, located 1.9 cm from the plate edge, through which one of the curved surgical needles would pass. Four screws were placed through the plates to firmly secure the glove membrane or membranes. The support plates were then set on top of the load cell, which was then calibrated in grams.

Glove samples were taken from the tubular area of the glove near the cuff and secured between the support plates, allowing a uniform strain to be placed upon the glove membrane or membranes by the pulling clamp. The curved surgical needle was positioned above one of the puncture holes and then moved downward at a rate of 10 mm/min. After glove membrane puncture, the needle movement was stopped and returned to the starting position. The plate was then rotated to align another puncture hole, and the process was repeated. The force applied to the load cell was graphed throughout the process by a strip chart recorder. The maximum puncture resistance force was measured by the compression load cell and recorded in grams with a strip chart recorder. Ten puncture resistance measurements for each needle were taken from five samples of the Biogel® Indicator™ underglove, Biogel® Super-Sensitive™ glove, Biogel® glove, Biogel® Skinsense® N Universal underglove, Biogel® Skinsense® Polyisoprene glove, Biogel® Skinsense® Polyisoprene double-glove hole puncture indication system, Biogel® Super-Sensitive™ double-glove hole puncture indication system, and the Biogel® double-glove hole puncture indication system. The computer system calculated the means and standard deviations of the puncture forces of each of the three curved surgical needles for the different glove samples. The statistical significance of the data was determined by the Student's test.

The magnitude of the puncture resistance forces encountered was influenced by three factors: (1) the glove material, (2) the number of glove layers, and (3) the type of surgical needle. For each type of curved

surgical needle, the resistance to needle penetration by the non-latex gloves was significantly greater than that encountered by the latex glove material ($P < 0.001$). This enhanced resistance to glove puncture of the non-latex gloves was noted with both the non-latex underglove and the latex underglove. Blunting the sharp end of the taper point needle before penetrating the non-latex outer glove ($P < 0.001$) markedly increased its resistance to glove puncture in the latex and non-latex outerglove.

Using the same surgical needle type, the Biogel® Skinsense® Polyisoprene outer glove provided the greatest resistance to surgical needle puncture followed by the Biogel® Skinsense® N Universal underglove ($P < 0.001$). The resistance to needle puncture of all three double-glove hole puncture indication systems was significantly greater than that of either the non-latex or latex undergloves or outer gloves.

The taper point needle encountered the lowest puncture resistance forces in the five single gloves and three double-glove hole puncture indication systems ($P < 0.001$). Blunting the sharp end of the taper point needle markedly increased its resistance to glove puncture of the five single gloves as well as the three double-glove hole puncture indication systems ($P < 0.001$). The blunt-point surgical needle elicited the greatest needle penetration force of all of the single and double-glove hole puncture indication systems ($P < 0.001$).

Mast et al. developed both an *in vitro* and an *ex vivo* model of percutaneous needlestick injury and compared blood volumes transferred while varying exposure parameters.²⁰ They also evaluated the efficacy of latex and vinyl surgical gloves for blood transfer in both models. Needle size and depth of needle penetration had statistically significant correlation with the amount of blood volume transferred by hollow needles when surgical needles were tested. Only the depth of penetration had significant influence on the volume of blood transferred. The use of glove material of any type was associated with a reduction in blood volume transferred by both hollow-bore and suture needles. The observation that glove material may decrease the exposure volume by <50% during simulated needlesticks indicates that the risk of infection could be decreased when a needle passes through a glove before contacting skin. Even though the glove materials do not prevent all needlestick injuries, they may reduce infection risk even though there is skin penetration.

In 1994, Bennett and Howard further evaluated the quantity of blood inoculated in a needlestick injury from suture and hypodermic needles using an *in vitro* model.²¹ Their study quantified the amount of blood inoculums present on several commonly used surgical and phlebotomy needles. In addition, they determined the effect of single or double-gloving, depth of needle penetration, and needle size on inoculums volume. Nineteen gauge, 22 gauge, and 25 gauge phlebotomy needles, taper point surgical needles attached to 0, 3-0, and 5-0 sutures, as well as a cutting edge needle with a 4-0 suture were evaluated. The needles were positioned into blood labeled with epidermal growth factor and then embedded 2 or 5 mm into an agarose gel. The volume of blood inoculum varied from 133 to 683 nL for the phlebotomy needles and from 35 to 366 nL for surgical needles. These different needles were then passed through two, one, or no layers of surgical glove material before embedding the needles 5 mm into agarose gel. They reported that the use of one layer of surgical glove resulted in a significant ($P < 0.001$) decrease in inoculum from taper point needles, but not from cutting edge needles. They noted that double-gloves were even more efficient ($P < 0.001$) than one glove in removing blood from all suture needles, including the cutting edge surgical needle. In contrast, surgical glove material did not significantly reduce the volume of blood inoculum transferred by phlebotomy needles.

As in the above *in vitro* investigations, a wide variety of surgical specialists have provided convincing evidence that double-gloving protects the operating room staff from skin contamination during accidental surgical needle puncture. In 1997, Marin-Bertolin et al. evaluated the effectiveness of double-gloving in maintaining an intact barrier between the patient and the hands of the surgical staff during plastic surgical operations.²² For 2 months, the surgical staff of a plastic surgery unit randomly wore single or double-gloves during all elective surgical procedures. All operating room personnel wore latex double-gloves, except one of the surgeons with chronic eczema of the hands who wore vinyl undergloves. One pair of unused latex gloves was selected at random in one of four of all the operative procedures and tested for perforations. The perforation rate of the control as well as the operative gloves was determined using the water leak method. It was gratifying to find that the 54 control gloves had no perforations. During the 107 operations, the parenteral exposure rate

was 9.3% (10 of 107). All exposures were a result of surgical needle puncture. The perforation rate for the single glove (7.3%) was similar to that for the outer glove of the double-glove system (9.8%). They reported that the perforation rate for the underglove of the double-glove system (3%) was significantly lower than those of the single gloves or outer gloves of the double-glove systems ($P < 0.05$). The investigators concluded that double-gloving reduced the risk of skin contamination in plastic surgical procedures.

In 1999, Hollaus et al. examined the glove perforation rate of the latex double-glove hole puncture indication system during 100 thoracotomies.²³ The outer gloves were the Biogel[®] Super-Sensitive[™] glove. The underglove was the green Indicator[™] glove. Perforation of the outer gloves allowed inflow of fluid between the two pairs of gloves. The wet area of the underglove then appeared as a green spot through the translucent outer glove once the outer glove had a perforation. Because Brown²⁴ demonstrated a 100% accuracy of this double-glove hole puncture indication system, Hollaus et al. used this modality rather than the water leak test as evidence of glove hole puncture.²⁴ The investigators reported 150 outer glove perforations (8.9%) and only 19 underglove perforations (1.1%). On the basis of these results, they concluded that cutaneous blood exposure was prevented in 78% of all operations. They indicated that double-gloving should become a routine for thoracic surgeons, to prevent transmission of bloodborne infections.

Despite the dangers of transmission of bloodborne pathogens many surgeons are reluctant to use double-gloves for a variety of reasons.¹ Some do not see the need and ignore the overwhelming evidence of bloodborne transmission of infections during surgery.² Others complain of symptoms of hand tingling, numbness, or pain while wearing double-gloves. Others note decreased hand sensitivity, which interferes with manipulation of instruments.

Consequently, Novak et al. assessed the hand sensitivity of surgeons without surgical gloves, with single gloves, and with double-gloves.² They performed a sensory evaluation that included cutaneous pressure threshold, moving two-point discrimination, and static two-point discrimination. The cutaneous pressure thresholds varied from 1.65 to 3.22 with no gloves, 2.44 to 3.61 with single gloves, and 3.22 to 4.17 with double-gloves. It was interesting that the moving two-point discrimination was 2 mm in the majority

(22 of 25) of surgeons. They reported that the lowest cutaneous pressure thresholds were noted when measured with no gloves and increased with single and double-gloves. Statistically significant differences in cutaneous pressure thresholds were found for gloves versus no gloves and single versus double-gloves. In addition, statistically significant differences in moving two-point discriminations were identified in single versus double-gloves. The investigators concluded that double-gloves do indeed impair hand sensation. They did, however, point out that the surgeon will be able to find the correct and comfortable fit for double-gloves after a trial period that takes approximately 1 to 120 days. They suggest that the perception of decreased sensation experienced by the surgeon when first using double-gloves will likely be minimized and overcome with sensory cortex remapping.

The U.S. Food and Drug Administration mandates that the glove hole leakage rate of manufactured sterile surgical gloves must not exceed 1.5%. It is surprising to the authors of this collective review that the potential glove leakage rate is not listed on every sterile glove package, which would remind operating room personnel that a significant number of sterile surgical gloves have holes, an invitation to the spread of deadly bloodborne viral infections between the patient and the surgeon. Moreover, it is very disappointing that the Food and Drug Administration has still not banned the use of powder on sterile surgical gloves that potentiates tissue toxicity and infection, as well as adhesions, and remains as a vector for the latex allergy epidemic.²⁷

It is important to emphasize that the hospital setting in which double-glove hole systems are used has an important influence on the accuracy of the system to detect holes in the outer glove. Fisher et al. documented the performance of the double-glove hole indication system in the emergency department.²⁸ In their study, the frequency of holes in both gloves of the double-glove hole indication system was determined using a watertight test method. Second, the frequency of glove puncture was determined first by searching for the optical color change that occurs when the ingress of fluid occurs in the double-glove hole detection systems. In 50 consecutive patients, there was no color change in the inner glove that would indicate glove puncture. When the same gloves were then tested with the watertight test method, 14 of 50 double-glove hole indication systems had indication of glove puncture. The failure of the physi-

cians to detect visual changes at the site of glove hole puncture was due to the absence of a wet surface over the outer glove. Because it is difficult to wet the outer surface of the glove with sterile saline in the emergency department, the double-glove hole indication system has no value in detecting glove puncture in the emergency department.

References

1. Carl M, Francis DP, Blakey DL, Maynard JE. Interruption of hepatitis B transmission by modification of a gynaecologist's surgical technique. *Lancet*. 1982; 1:731-733.
2. Pattison CP, Maynard JE, Berquist KR, Webster HM. Epidemiology of hepatitis B in hospital personnel. *Am J Epidemiol*. 1975; 101:59-64.
3. McKinney WP, Young MJ. The cumulative probability of occupationally-acquired HIV infection: the risk of repeated exposures during a surgical career. *Infect Control Hosp Epidemiol*. 1990; 11:243-247.
4. Hussain SA, Latif AB, Choudhary AA. Risk to surgeons: a survey of accidental injuries during operations. *Br J Surg*. 1988; 75:314-316.
5. Wright JG, McGeer AJ, Chyatte D, Ransohoff DF. Mechanisms of glove tears and sharp injuries among surgical personnel. *JAMA*. 1991; 266:1668-1671.
6. Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS, Marlone WJ. Percutaneous injuries during surgical procedures. *JAMA*. 1992; 267:2899-2904.
7. Montz FJ, Fowler JM, Farias-Eisner R, Nash TJ. Blunt needles in fascial closure. *Surg Gynecol Obstet*. 1991; 173:147-148.
8. Wright KU, Moran CG, Briggs PJ. Glove perforation during hip arthroplasty. A randomized prospective study of a new taperpoint needle. *J Bone Joint Surg Br*. 1993; 75: 918-920.
9. Brough SJ, Hunt TM, Barrie WW. Surgical glove perforations. *Br J Surg*. 1988; 75:317.
10. Miller SS, Sabharwal A. Subcuticular skin closure using a "blunt" needle. *Ann R Coll Surg Engl*. 1994; 76:281.
11. Dauleh MI, Irving AD, Townell NH. Needle prick injury to the surgeon--do we need sharp needles? *J R Coll Surg Edinb*. 1994; 39:310-311.
12. Bell DM, Shapiro CN, Ciesielski CA, Chamberland ME. Preventing bloodborne pathogen transmission from health-care workers to patients. The CDC perspective. *Surg Clin North Am*. 1995; 75:1189-1203.
13. Lewis FR Jr, Short LJ, Howard RJ, Jacobs AJ, Roche NE. Epidemiology of injuries by needles and other

- sharp instruments: minimizing sharp injuries in gynecologic and obstetric operations. *Surg Clin North Am.* 1995; 75:1105-1121.
14. Hartley JE, Ahmed S, Milkins R, Naylor G, Monson JR, Lee PW. Randomized trial of blunt-tipped versus cutting needles to reduce glove puncture during mass closure of the abdomen. *Br J Surg.* 1996; 83:1156-1157.
 15. Mingoli A, Sapienza P, Sgarzini G, Luciani G, De Angelis G, Modini C, Ciccarone F, Feldhaus RJ. Influence of blunt needles on surgical glove perforation and safety for the surgeon. *Am J Surg.* 1996; 172:512-517.
 16. Centers for Disease Control and Prevention. Evaluation of blunt suture needles in preventing percutaneous injuries among health-care workers during gynecologic surgical procedures--New York, March 1993-June 1994. *MMWR Morb Mortal Wkly Rep.* 1997; 46:25-29.
 17. Berridge DC, Starky G, Jones NA, Chamberlain J. A randomized controlled trial of double- versus single-gloving in vascular surgery. *J R Coll Surg Edinb.* 1998; 43:9-10.
 18. Edlich RF, Wind TC, Hill LG, Thacker JG, McGregor W. Reducing accidental injuries during surgery. *J Long Term Eff Med Implants.* 2003; 13: 1-10.
 19. Standard Test Method for Protective Clothing Material Resistance to Puncture. American Society for Testing and Materials F1342-91 (Reapproved 1996).
 20. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. *J Infect Dis.* 1993; 168:1589-1592.
 21. Bennett NT, Howard RJ. Quantity of blood inoculated in a needlestick injury from suture needles. *J Am Coll Surg.* 1994; 178:107-110.
 22. Marin-Bertolin S, González-Martinez R, Gimenez CN, Vila PM, Amorrortu-Velayos J. Does double gloving protect surgical staff from skin contamination during plastic surgery? *Plast Reconstr Surg.* 1997; 99:956-960.
 23. Hollaus PH, Lax F, Janakiev D, Wurnig PN, Pridun NS. Glove perforation rate in open lung surgery. *Eur J Cardiovasc Surg.* 1999; 15:461-464.
 24. Brown JN. Surgeon protection: early recognition of glove perforation using a green under glove. *J R Coll Surg Edinb.* 1996; 41:395-396.
 25. Patterson JM, Novak CB, Mackinnon SE, Patterson GA. Surgeons' concern and practices of protection against bloodborne pathogens. *Ann Surg.* 1998; 228:266-272.
 26. Novak CB, Patterson JM, Mackinnon SE. Evaluation of hand sensibility with single and double latex gloves. *Plast Reconstr Surg.* 1999; 103:128-131.
 27. Edlich RF, Woodard CR, Pine SA, Lin KY. Hazards of powder on surgical and examination gloves: a collective review. *J Long Term Eff Med Implants.* 2001; 11:15-27.
 28. Fisher MD, O'Keefe JS, Williams FM, Neal JG, Syverud SA, Edlich RF. Failure of a new double glove hole detection system in the Emergency Department. *J Biomed Mater Res.* 1999;48(2):199-201.

Scientific Basis for the Selection of Surgical Staples and Tissue Adhesives for Closure of Skin Wounds

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During the last four decades, there have been revolutionary advances in the development of skin staples as well as tissue adhesives. One of the purposes of this collective review is to provide an overview of recent advances in the development of metal and absorbable skin staples and tissue adhesives. In addition, we will provide technical considerations in the use of metal and absorbable skin staples and tissue adhesives during surgery. On the basis of extensive experimental studies, we would recommend the Autosuture™ Multifire Premium™ metal skin stapler. During a surgical operation, the rotating head of this skin stapler can have its skin stapling cartridge removed once for additional stapling. The revolutionary Insoorb™ subcuticular skin stapler is designed to combine the cosmetic result of absorbable sutures with the rapid closure times associated with metal skin staplers, while eliminating the need for metal staple removal postoperatively. The Insoorb™ absorbable staple is composed of a copolymer that is predominantly polylactide, which is absorbed over a period of a few months. The superior performance of the Insoorb™ absorbable staple has been confirmed by experimental and clinical studies. In the last 20 years, surgeons have become increasingly interested in replacing sutures by means of adhesive bonds in the closure of surgical wounds. A recent collective review of clinical studies done with tissue adhesive has recommended that there is a need for well-designed randomized, controlled trials comparing tissue adhesives and alternate methods of closure, especially in patients whose health may interfere with wound healing.

KEY WORDS: metal skin staple, absorbable skin staple, tissue adhesive, wound infection, wound dehiscence

Introduction

During the last four decades, there have been revolutionary advances in the development of skin staples as well as tissue adhesives. One of the purposes of this collective review is to provide an overview of recent advances in the development of skin staples and tissue adhesives. We will provide technical considerations in the use of skin staples and tissue adhesives during surgery. In addition, we will provide scientific information that will allow you to select skin staples and tissue adhesives that have the least risk for infection and allow wound closure to be achieved with the most aesthetically pleasing scar.

Skin Staples

The use of mechanical means for wound closure first appeared in ancient Hindu medicine. Insect mandibles were employed for wound closure in the jungles of southern Bhutan at the foot of the Himalayas.¹ Victor Fischer, an ingenious designer of surgical instruments, was the inventor of the first surgical stapler that used metal staples.² He designed and developed different gastrointestinal (GI) staplers for Hümér Hütl, one of the leading surgeons at the St. Rokus Hospital in Budapest. Hütl operated on his first patient with the stapler on May 9, 1908. The stapling instrument was very bulky and cumbersome, weighing 5 kg and taking two hours to assemble. In 1920, Aladár von Petz, a young surgical assistant at the University of Budapest, designed a stapler weighing only 1 kg that became the prototype for future GI staplers.

Subsequently, a great impetus to mechanical stapling devices was given by the Institute for Experimental Surgical Apparatus and Instruments in the mid-1950s.³ The early experience of Steichen and Ravitch with the original Soviet staplers convinced them of their potential uses in surgery, which provided the stimulus for American designers and manufacturers to create a family of staplers.⁴ Although many of the original staplers were developed from the basic principles utilized in the Soviet instruments, the skin stapler was a totally new kind of instrument in conception. This stapler, manufactured in the United States (Autosuture™, US Surgical, division of Tyco Healthcare, Norwalk, CT), utilized a disposable, preloaded, presterilized magazine that contained 25 staples. A small sterile disposable cylinder contain-

ing carbon dioxide provided the driving force for the formation of rectangular skin staples. Steichen and Ravitch⁴ reported that this instrument saved considerable time during the operative procedure.

The first major change in the design of this skin stapler was to replace the carbon dioxide cartridge with a mechanical power source, a movable handle.⁵ By compressing the movable handle against a fixed handle, the surgeon generated sufficient force to form the rectangular staple. This metal stapler, which had to be cleaned and autoclaved before each surgical procedure, employed a sterile, disposable cartridge containing 25 to 35 staples that were easily positioned in the delivery end of the stapler. The time required to clean and autoclave these staplers was circumvented by then developing sterile disposable skin staplers.⁶

It is one of the purposes of this report to describe the scientific basis for the selection of skin stapling techniques. By understanding the influence of these staple closure devices on the biology of wound repair and infection, the surgeon can accomplish staple closure with the most aesthetically pleasing scar and with the lowest incidence of infection. Skin staplers can be divided into those that deliver metal skin staples and those that deliver absorbable skin staples.

Metal Skin Staples

Metal skin staples are one of the most common techniques of approximating the skin. When selecting a metal skin stapler, the surgeon must consider the following features: design specifications and surgical performance.

Design Specifications

The surgeon's selection of a disposable stapler is determined by several important parameters of mechanical performance, including 1) handling characteristics, 2) maximal angle of visual access to the staple, 3) angle at which the staple enters the tissue, 4) ease of positioning, 5) prepositioning mechanism for staple, 6) staple release mechanism, 7) texture, and 8) weight.

Stapler design must strive to diminish energy expenditure.⁷ The weight of the stapler is an important consideration to avoid hand fatigue. Using light tools for light tasks is a worthwhile rule. The investigations

of Comaish and Bottoms⁸ and Naylor⁹ provide a basis for including texture among the important design elements of staplers. A slippery finish demands energy expenditure for retention in the surgeon's hands. Texture that is too coarse can lead to discomfort, skin irritation, and diminished efficiency. Actuating the stapler should be accomplished with ease. Strength differences between men and women provide a basis for using women's strength as a standard when determining forces needed to form staples. Once the staple is formed, all stapler handles are spring-loaded, which returns them to their resting position, reducing work expenditure.

Staplers operated by grip activity with a rotating head remain the most popular skin closure staplers. All staplers are designed with fixed and movable handles. For skin staplers operated by grip activities, the surgeon usually compresses the movable handle with the index, long, ring, and little fingers against the fixed handle, which is stabilized against the plane of the hand.¹⁰ The distance between the movable and stationary handles is an important consideration in stapler design. Surgeons prefer to compress a movable handle whose contact surface is 5.5 to 8.0 cm from the contact surface of the stationary handle, because they can exert maximal grip strength at these distances without becoming fatigued.¹¹ When this distance is short (≤ 3.0 cm), the surgeon's grip strength on the movable and fixed handles is limited, predisposing to fatigue after repeated staple formations.

A surgical skin stapler should have a rotating head to provide optimal visualization of the underlying wound. By rotating the stapler head, the stapler can be adjusted so that the instrument does not obstruct the surgeon's view of the wound edge. An important additional feature of the skin stapler is its prepositioning mechanism, which allows the surgeon to hold the staple in various positions during its formation. A clutch-like mechanism has been incorporated into the stapler, which allows the surgeon to release pressure on the moveable stapler handles without losing control of the partially formed staple. The delivery end of the skin stapler cartridge should assume a 60° angle with the underlying skin, which provides intimate contact with the skin with only a 1 mm deep recess in which the staple is formed. When the staple is delivered to the wound at this 60° angle, it tends to assume an upright position that is perpendicular to the wound. This additional space allows the entrapped tissue to expand during healing without contacting

the staple topspan, thereby decreasing the likelihood of the development of transverse skin scars (cross-hatching) beneath the topspan.

Once the staple is formed, the stapler should have an automatic release system that separates the staple from the stapler. After firing all of the staples in a cartridge, the cartridge should be removed from the instrument and replaced with a new cartridge if additional staples are needed to staple the incision or graft. Finally, the handling characteristics of the stapler should be such that the surgeon can easily implant a large number of staples without becoming fatigued.

Like surgical needles, the configuration and position of the pointed legs of the staple may influence the performance of the stapler. The geometry of the staple should assume a rectangular shape in the tissue. The uniform geometry of the stainless steel staples has been attributed to both the position of dimples, or indentations, in the staple wire, and to the geometry of the staple wire. Dimples or indentations in the wire have been inset at the junction of the topspan and its legs. These dimples facilitate the positioning of the wire on the anvil and the creation of a uniform staple. In addition, the flattened topspan of the staple gains intimate contact with the anvil, which contributes to uniform staple geometry. In our extensive experience with skin stapling, we prefer rotating head skin staplers.

Rotating Head Skin Staplers

Rotating head skin staplers are now produced by two different manufacturers. Covidien (Norwalk, CT) produces the AutosutureTM Multifire PremiumTM, while Ethicon, Inc., (Somerville, NJ) manufactures the Proximate RHTM.

AutosutureTM Multifire PremiumTM. The AutosutureTM Multifire PremiumTM disposable skin stapler is unique in that its cartridge may be reloaded, allowing for multiple uses during a single surgical procedure (Fig. 1). This stapler functions like a pistol stapler and is lightweight, weighing less than 98 g. Each Multifire PremiumTM disposable skin stapler has two components: a loading unit and a cartridge. The instrument has one fixed and one movable handle that are attached to the stapler delivery body through which the cartridge is loaded. The movable handle of the loading unit extends from the fixed handle at a 45° angle resulting in an 8.0 cm distance between the contact surfaces of its handles. The contact surface



Figure 1. Autosuture™ Multifire Premium™ disposable skin stapling instrument.

of the movable handle has a deep scallop that accommodates the surgeon's index finger.

The delivery end of the loading unit has a stationary component that is attached to a rotating hollow plastic nose through which the cartridge is inserted. The plastic nose is tapered and short (4.8 cm), so that it does not interfere with the surgeon's sight of the wound. The loading unit accepts cartridges containing either wide or regular size staples, both of which have a rectangular shape with a beveled delivery end. The length and thickness of the cartridge for the regular and wide staples are identical, being 10.1 cm and 7 mm, respectively. The width (1.6 cm) of the cartridge with the regular size staples is smaller than that of the cartridge with the wide staples (2.1 cm).

The delivery end of the Multifire Premium™ disposable skin stapler cartridge assumes a 60° angle, which provides intimate contact with the skin and with only a 1 mm deep recess in which the staple is formed. When the staple is delivered to the wound at a 60° angle, it tends to assume an upright position that is perpendicular to the wound. This additional space allows the entrapped tissue to expand during healing without contacting the topspan, thereby decreasing the likelihood of the development of skin scars (cross-hatching) beneath the topspan. Directional arrows made of paper with an adhesive backing are attached to the top and bottom surfaces of the cartridge to indicate the site to which the staple is delivered.

The Multifire Premium™ disposable skin stapler was designed for multiple uses during a single operative procedure. The most obvious advantage of this

feature is that it substantially reduces the cost of skin stapling during surgery that involves multiple cartridges. The need for multiple cartridges is especially evident in the fixation of multiple skin grafts during reconstructive surgery. Today, the Multifire Premium™ stapler is limited to only one cartridge change before a new skin stapler must be used.

Forceps approximate the skin edges before stapling. Stapling is accomplished in a manner so that there is sight of each formed staple. With the surgeon standing at the patient's right side, skin stapling is begun at the cephalad end of incisions. Stapling from the caudad to cephalad direction is technically more challenging because the surgeon's hand and stapler will interfere with sight of previously formed staples, accounting for errors in staple placement that may result in misalignment of the wound edges.

By rotating the stapler handles toward the surgeon, sight of the skin edges becomes easier. The rotated delivery end of the stapler is positioned above the divided skin edges. An important additional feature of the Multifire Premium™ disposable skin stapler is its staple prepositioning mechanism, which allows the surgeon to hold the staple in various positions during its formation. A clutch-like mechanism has been incorporated into this stapler, which allows the surgeon to release pressure on the movable staple handle without losing control of the partially formed staple. Precocking of the instrument occurs when the topspan of the unformed staple rests against the anvil with exposure of the staple legs beyond the stapler delivery end. Precocking of the stapler requires only a small degree of rotation (squeeze) of the movable



Figure 2. Proximate RH™ disposable skin stapling instrument.

handle (9.5°) with insignificant force, because the staple is not deformed. Consequently, the surgeon can precisely and repetitively expose the staple legs, which are strong enough to be used as skin hooks that facilitate approximation of the divided skin edges.

Once the staple is formed, the stapler has an automatic release mechanism that separates the staple from the stapler. The Multifire Premium™ disposable skin stapler cartridges contain 12, 25, or 35 staples. After firing all of the staples in a cartridge, the cartridge should be unloaded from the disposable instrument and replaced with a new cartridge if additional staples are needed to staple the incision.

Proximate RH™ Stapler. The Proximate RH™ stapler has an external surface made of a smooth polished plastic and functions like a pistol stapler (Fig. 2). It is lightweight, weighing less than 122 g. The stapler has one fixed and one movable handle that are attached to the delivery end of the stapler, which has a rotating head. The stationary handle of the Proximate RH™ stapler attaches to its delivery end at an oblique angle of 30° from the vertical axis. The longest distance between the contact surfaces of the stationary and movable handles of the Proximate RH™ stapler is 8.0 cm. A shallow scallop, or flare, is evident on the contact surface of the movable handle to facilitate positioning of the surgeon's index finger.

The delivery end of the Proximate RH™ stapler has a stationary part that is attached to its rotating end. Its rotating end has two components. Its proximal

position has a tapered plastic sleeve (length 4.0 cm) through which a planar-shaped cartridge (length 6.3 cm) passes to become the delivery end of the stapler. The cartridges for the regular and wide staples of the Proximate RH™ stapler are the same size. The cartridge has a linear slit that allows sight of the number of staples. Once all the staples are fired from the stapler, the surgeon must use a new stapler because its cartridge is fixed to the delivery end of the stapler and is, therefore, not reloadable.

The delivery end of the Proximate RH™ cartridge has two distinct parts. Its distal portion (1.8 cm width) with a 1 mm deep recess is flat and contacts the skin surface so that the stapler delivers its staples at a 90° angle to the tissue. The remaining portion is recessed 3 mm from the distal portion (1.6 cm width) and has a flat surface that does not contact the skin. An engraved black arrow on the top of the cartridge indicates the site to which the staple is delivered.

The 90° angle at which the Proximate RH™ staple delivers its staples has several implications. This staple delivery angle limits the surgeon's ability to visualize the staple as it penetrates the tissue. Consequently, the surgeon cannot easily control the depth that the staple legs penetrate the tissue. The surgeon may implant the staple deeply in the tissue with its topspan flush with the skin. Such a deeply implanted staple may induce several damaging effects on the tissue. First, it can strangulate the entrapped tissue, and thereby reduce its resistance to infection. Second, it

may abrade the underlying skin, which may result in permanent transverse scars.

The Proximate RH™ stapler forms a rectangular-shaped staple. Its unformed staple has a unique configuration. V-shaped legs extend from its straight tospan. For this unformed staple to assume a rectangular shape, its legs must rotate 120°. Its unique unformed shape permits an in-line staple-to-staple stacking arrangement which, by itself, seems quite reliable. This stack, however, requires a mechanism to transfer the lead staple to the firing position, and thereby introduces an additional mode of failure (eg, jamming).

Precocking of the Proximate RH™ stapler to a site at which the staple legs are visible beyond the staple delivery end requires considerable force and movement of the movable handle. In contrast to the Multifire Premium™ stapler, the unformed staple must be deformed to allow visualization of the staples pointed legs. This staple deformation is associated with substantial rotation (16.5°-19.5°) of the stapler's movable handle. Because prepositioning of the Proximate RH™ staple leg involves considerable handle movement by substantial forces, it precludes delicate manipulation of the divided skin edges by the exposed staple legs. Once the staple is formed, the Proximate RH™ stapler has an automatic release mechanism that separates the staple from the stapler.

A comprehensive study by Jones and colleagues compared the performance of the Multifire Premium™ and Proximate RH™ disposable skin staplers in an experimental and clinical investigation.¹²

Experimental Evaluation. Stapler performance for the Multifire Premium™ and Proximate RH™ was determined by four parameters: force required to form the staple, staple sharpness, uniformity of the staple geometry, and clinical performance. The force required to form the staple is an important factor in assessing stapler performance. Ideally, staple formation should be accomplished with relative ease and without fatigue. Although the distances between the contact surfaces of the movable and stationary handles of the Multifire Premium™ and Proximate RH™ staplers were remarkably similar (8.0 cm), the investigators reported significant differences between the forces required to form their regular and wide staples using these staplers.¹² The forces required to form the Multifire Premium™ regular and wide staples were significantly less than those needed to form the corresponding Proximate RH™

regular and wide staples ($P < 0.05$). The forces needed to form the Proximate RH™ wide staples were the greatest

Point-sharpness of the skin staple was determined by measuring the maximum vertical force required for it to penetrate a thin synthetic membrane.¹² Although the diameter of the regular size staples was less than that of the wide staples, the forces required for the regular and wide staples to penetrate the thin synthetic membrane did not differ significantly. However, the manufacturing process appeared to have considerable influence on staple sharpness, as measured by the penetration forces. The Multifire Premium™ regular and wide staples encountered significantly lower penetration forces than the regular and wide Proximate RH™ staples ($P < 0.05$).

The metal staples had similar composition, being made of 316L stainless steel. The surfaces of staples may be coated with polymers to facilitate passage through tissue. The manufacturers did not identify the presence of surface coatings and their exact composition. The dimensions of the unformed and formed staples from the staplers were determined by measurements made with a Model TM 20 Nikon Toolmaker Microscope (Tokyo, Japan). The uniformity of the geometry of random samples of the formed staples and the pointed legs was ascertained by photographs at 10 × and 25 × magnifications, respectively. The Multifire Premium™ regular and wide staples formed by the stapler, without penetrating the skin, had a remarkably uniform geometry.¹² In contrast, the geometry of the regular and wide staples formed by the Proximate RH™ stapler showed considerable variability. This disparity in the shapes of the staples had considerable influence on the position of the pointed legs underlying the staple tospan. In some cases, the distances between the pointed legs of the Proximate RH™ staple varied, while in other cases the pointed legs were not in or on the same geometric plane.

Clinical Evaluation. Five surgeons during surgical procedures that involved skin closure accomplished a clinical evaluation of the Multifire Premium™ disposable skin stapler and Proximate RH™ stapler.¹² For each stapler, the surgeon commented on the staple prepositioning mechanism, visibility of staple during its formation, uniformity of staple geometry, relative force required to form the staple, frequency and type of stapler malfunction, as well as any perceived advantages and disadvantages of the staplers.

In this clinical study, the Multifire Premium™ disposable skin staplers were favored over the Proximate RH™ staplers for closure of incisions. The surgeons noted that the major advantage of the Multifire Premium™ disposable skin stapler was that its cartridge could be reloaded. This reloading capability of the Multifire Premium™ disposable skin stapler did require limited training of the user to prevent unnecessary malfunction of the stapler. They preferred the handling characteristics of the Multifire Premium™ disposable skin stapler to the Proximate RH™ skin stapler. They noted that they could preposition (precock) the Multifire Premium™ disposable skin stapler with less force than the Proximate RH™ stapler, allowing them easier use of the pointed legs of the Multifire Premium™ staples as skin hooks to facilitate approximation of the divided edges of skin. They favored the delivery end of the Multifire Premium™ disposable skin stapler over that of the Proximate RH™ stapler, because the beveled delivery end of the Multifire Premium™ disposable skin stapler delivered the staple at a 60° angle to the wound surface. As the staple rotated to a 90° angle, it left a space between the skin and topspan, allowing easy staple removal. In contrast, the surgeon usually held the delivery end of the Proximate RH™ stapler perpendicular to the underlying wound, making it difficult to visualize and control the depth of penetration of its staple legs.

Surgeons could repeatedly use the Multifire Premium™ disposable skin staplers with either wide or regular staples as well as the Proximate RH™ staplers with regular staples without fatigue. However, surgeons noted that the forces to form Proximate RH™ wide staples were excessive and could predispose the surgeons to fatigue. Moreover, they were impressed by the uniform geometry of the formed regular and wide Multifire Premium™ staples that facilitated meticulous approximation of the divided skin edges. In contrast, they noted the non-uniform geometry of the regular and wide Proximate RH™ staples appeared to distort the wound edges. In addition, one out of three Proximate RH™ staplers became jammed during wound closure so that staples could not be delivered into the skin. In contrast, staple jamming of the Multifire Premium™ disposable stapler was not encountered, unless the surgeon did not reload a new cartridge properly.

The influence of staples and their configuration on the biology of skin wound repair and infection has

been the subject of increasing numbers of scientific studies. Jewell and colleagues compared the healing of sutured wounds to that of stapled wounds in the rat.¹³ The skin incisions in one experimental group were closed with regular-sized Proximate RH™ staples implanted at 5 mm intervals, whereas interrupted 4-0 monofilament nylon sutures approximated skin incisions in the remaining group at 5 mm intervals. Staples and sutures were removed from the wounds on the seventh postoperative day. No significant difference was reported between the mean breaking strength of the wounds with either staples or sutures at 10, 42, and 180 days after closure. However, there was a significant difference in the breaking strength at 21 days, the sutured wounds being slightly stronger than the stapled wounds.

There is uniform agreement that skin wounds closed by staples exhibit a superior resistance to infection than skin wounds contaminated by the least reactive suture. In an experimental study, Johnson and colleagues compared the resistance to infection of contaminated wounds approximated by tape, staples, or sutures.¹⁴ Skin wounds closed by tape exhibited the greatest degree of resistance to infection, followed by the stapled wounds, and then the wounds approximated by the least reactive nonabsorbable sutures. The superiority of tape closure was evident at all levels of contamination, except 5×10^7 bacteria at which all wounds were destined to develop infection regardless of the closure technique. In the presence of lower bacterial inocula, wounds approximated by staples exhibited a lower rate of infection than the least reactive nonabsorbable suture, monofilament nylon. The infection rate in these wounds correlated with the wound bacterial counts. Sutured wounds exhibited the highest bacterial counts, followed by stapled wounds and then taped wounds. The superior resistance of stapled wounds to infection as compared with the resistance of sutured wounds was confirmed by the experimental study of Stillman and colleagues.¹⁰ In contaminated wounds in mice, stapled wounds displayed a lower incidence of infection than wounds approximated by either percutaneous sutures (4-0 silk, 4-0 monofilament nylon, and 4-0 polyglycolic acid suture) or subcuticular sutures (4-0 polyglycolic).

In a busy clinical setting, there exists a need for fast, safe, and cost effective methods of wound repair. In animal models, stapled and sutured wounds displayed similar mechanical and histologic character-

istics, and contaminated wounds demonstrated lower infection rates when stapling was employed.¹⁵ Staple repair also provided other advantageous results, including decreased inflammatory response, wound width, and wound closure times, as well as promotion of wound-edge eversion, formation of an incomplete loop with decreased tissue strangulation, and a lack of residual cross marks.^{16,17}

Kanegaye and colleagues¹⁸ conducted a study of a pediatric emergency department to determine the cost effectiveness and timesaving benefit of using staples in place of sutures. It was determined that staples were six times faster than standard sutures in the closure of scalp lacerations and eight times faster per centimeter. The results of staple use demonstrated a 29% decrease in the cost of surgical supplies, and an overall 30% to 40% decrease in the combined costs of supplies and physician compensation. The results of this study are comparable to studies involving adult patients.^{19,20} Orlinsky and colleagues²¹ also studied the costs related to both equipment and personnel time in stapling and suturing procedures and found staples to be cost effective for all surgical procedures examined.

Absorbable Skin Staples

The revolutionary Inorb™ Subcuticular Skin Stapler is designed to combine the cosmetic result of absorbable sutures with the rapid closure times associated with metal skin staplers, while eliminating the need for metal staple removal postoperatively. The patented Inorb™ 20 Subcuticular Skin Stapler (Incisive Surgical, Inc.,™ Plymouth, Minnesota) is a sterile, single-patient-use device that deploys up to 20 staples, which is sufficient to close a 17 cm incision. The Inorb™ absorbable staple is composed of a copolymer that is predominantly polylactide, which is absorbed over a period of a few months. In 10 weeks, the mass of this staple is approximately one-half of its original size.

This stapler uses a novel method of dermal closure that presents the dermis and then precisely places an absorbable staple in a horizontal, subcuticular, and interrupted manner to provide a secure, well-approximated everted dermal closure. The staple design features a U-shaped curvature with cleats at the two distal ends to secure the subcuticular tissue.

In 2006, our team of gifted scientists examined the performance of the Inorb™ stapler as com-

pared to suture and metal staplers.²² Six pigs were used to evaluate the influence of three separate modalities on contaminated wounds. Full-thickness skin wounds on the abdomen were contaminated with 10 x 4 or 10 x 5 *Staphylococcus aureus* and then closed with one of three methods. The three closure modalities included (1) a new absorbable staple (Inorb™) placed in the subcuticular tissue, (2) a braided Vicryl™ suture, and (3) percutaneous metal staples. Any foreign body or material implanted in tissue increases the risk of infection at that site. Wound closure always involves the use of a foreign body. Historically, sutures have been the primary material used to close tissue. The newer synthetic sutures are significantly more biodegradable and cause less infection than sutures composed of protein, such as silk and catgut. Metal staples are also associated with a low risk of infection. Recently, Incisive Surgical, Inc. (Plymouth, Minnesota), has developed an absorbable polymer staple specifically for subcuticular skin closure. The purpose of this study was to compare the new Inorb™ staple to both an absorbable polymer suture and a metal staple. Wound infection was assessed 7 days after closure by clinical signs and quantitative bacterial swabs. The results demonstrated that wounds closed with Inorb™ staples had the lowest incidence (33%) of infection, followed by percutaneous metal staples (44%). All wounds (100%) closed with Vicryl™ suture became infected. The incidence of wound infection directly correlated with the level of quantitative bacterial count at analysis. The Inorb™ staple was associated with significantly reduced closure time, less inflammation and infection, and better aesthetic result compared to Vicryl™. Compared to metal staples, the Inorb™ subcuticular staplers demonstrated comparable closure time without the need for later staple removal. In conclusion, the closure of contaminated wounds with the Inorb™ staples is a superior choice to Vicryl™ suture because they have a significantly ($P = 0.009$) lower incidence of infection. The Inorb™ staple is a revolutionary advance in subcuticular skin stapling.

In 2009, Cross et al. published a prospective, randomized, controlled clinical study using the Inorb™ dermal staple device. Patients undergoing bilateral breast reconstruction with tissue expanders had one incision randomized to dermal closure with absorbable dermal staples. The contralateral side was closed with dermal sutures. During the expansion period,

wounds were assessed by a blinded plastic surgeon using the 13-point Vancouver Scar Scale. At the time of implant exchange, both scars were excised and examined for histologic signs of inflammation. Eleven patients (22 incisions) were enrolled in the study. The dermal stapler was four times faster than standard suture closure, reducing closure time by 10.5 minutes ($P \leq 0.001$). Overall, cost savings with the dermal stapler was \$220 per case. In the early postoperative period, the dermal stapler had a higher Vancouver Scar Scale score than sutures because of superior wound eversion, a beneficial characteristic for wound healing. By 4 months postoperatively, no significant difference in scar scores was found between interventions. At 6 months, histologic analysis suggested decreased inflammatory cell invasion of the dermal stapler-closed scar. Closure using the absorbable dermal stapler can be performed significantly faster than standard suture closure techniques, allowing for a more cost-effective incisional closure with equivalent cosmetic results.²³

Tissue Adhesives

In the last 20 years, surgeons have become increasingly interested in replacing sutures by means of adhesive bonds in the closure of surgical wounds. Cyanoacrylate tissue adhesives have been used for a number of medical applications including bronchopleural fistula repair, endoscopic treatment of ulcers, high risk intestinal anastomoses, middle ear surgery, and a mesh fixation for inguinal hernia repair.²⁴⁻²⁶ The most extensive use of adhesive bonds is, however, for repair of traumatic lacerations in the emergency department. There are several advantages for the use of adhesive bonds compared with the conventional sutures. First, tissue union can be achieved rapidly. Second, the need to remove sutures is eliminated. Third, application of adhesive bonds is significantly less painful than suturing, and the cyanoacrylate adhesives have a significant antimicrobial effect against Gram-positive organisms.²⁷

Doraiswamy et al. studied the three available tissue adhesives and compared their performance.²⁸ These tissue adhesives included the following: N-butyl-2-cyanoacrylate (Histoacryl®, B. Braun, Melsungen, Germany), 2-octyl-cyanoacrylate (Dermabond®, Ethicon, Inc., Somerville, NJ), and N-butyl 2-cyanoacrylate (Indermil®, Syneture™, Covidien, Norwalk, CT). Histoacryl® has been available for nearly fifteen years; Indermil® and Dermabond® were introduced

to the market during the last decade. Children presenting with uncomplicated wounds <2.5 cm and <6h since the injuries were studied. There were 17 children in each group. Results were compared for the individual tissue adhesive and the technique. The tissue adhesives were applied according to the manufacturer's instructions. For Dermabond®, the outer container is squeezed to break the inner container that releases the adhesive, and the adhesive is then applied over the approximated wound edges by smearing in contact with the wound. For Histoacryl®, the adhesive is squeezed and smeared over the approximated wound edges by the spatulous tip. In the case of Indermil®, the adhesive is squeezed and applied over the approximated wound edges by droplet installation without contact. The caregiver's responses were recorded by direct questioning immediately after the procedure.

The use of tissue adhesives was, in general, satisfactory to all concerned: children, caregivers and staff. The glue effect was similar in all of the three tissue adhesives. It was found to be advantageous to use gloved fingers to approximate the wound edges. In the unfortunate event that the glove became stuck to the tissue adhesive, the glove had to be cut and left at the wound site, to prevent disrupting the wound while attempting to release the stuck glove. Use of the glove also helped to prevent adhesion of the user's finger directly to the edges of the wound as the glue finger on removal might disrupt the approximated wound edges. The investigators believe that Indermil® was the best choice among the three tissue adhesives. Parents should be warned of the persistence of scabs for scalp wounds for a maximum of 3.5 weeks in spite of washing hair.

Pelissier²⁹ provides comprehensive investigations of the use of Indermil® for wound closure of dorsal wounds with rabbits. A 4-cm-long and 1-cm-wide incision was created bilaterally on the backs of fifteen rabbits. A partial wound dehiscence occurred in the wound subjected to Indermil® in one animal at 2 weeks. In all other animals, no seroma, partial dehiscence, or wound infection occurred. Histopathologic analysis revealed that Indermil® induced edema and a mild acute inflammatory reaction, and reabsorbed completely in two months when applied to well vascularized tissue. The investigators concluded that the application of Indermil® on the cutaneous wound edges is a fast and easy procedure that does not seem to delay or inhibit the healing process or its quality.

Sinha et al. studied 50 patients who underwent a variety of hand operations and were randomized for wound closure either with tissue adhesive (Indermil®) or sutures.³⁰ The two treatment groups had similar demographic characteristics and similar outcomes at the 2- and 6-week postoperative assessments, which were performed by a designated tissue viability nurse blinded to the method of closure. Five minor wound dehiscences occurred: three in the adhesive group and two in the suture group. No infection occurred in either group. In conclusion, their study demonstrated tissue adhesive was as effective as suture in this type of hand surgery.

When cyanoacrylate tissue adhesive is topically applied to a wound site as a liquid, it polymerizes to a firm, pliable film that binds to epithelium and bridges the edges of a wound together. This film is sufficiently water resistant to permit showering by the patient after 48 hours and typically sloughs with keratinized epithelium 5 to 10 days after application. When compared with traditional skin closing techniques (sutures, staples, and adhesive tapes), certain cyanoacrylates have been repeatedly reported to be equal in effectiveness and safety for repair of lacerations and surgical incisions. Unlike sutures, cyanoacrylate tissue adhesives do not require special instrumentation or routine use of anesthesia for a removal procedure. They can also be applied more rapidly, and they decrease the amount of wound care from patients by serving as their own dressings. In addition, Osmond et al.²⁹ reported that cyanoacrylate tissue adhesive was more cost-effective compared with absorbable and nonabsorbable sutures for closing of pediatric facial lacerations.

In 2010, Coulthard et al. wrote a collective review on tissue adhesives for closure of surgical incisions.³² In their scientific report, studies documented that sutures were significantly better than tissue adhesives for minimizing dehiscence and were found to be significantly faster to use. Although surgeons may consider the use of tissue adhesives as an alternative to other methods of surgical site closure in the operating theatre, the authors emphasize that they must be aware that adhesives may take more time to apply and that if higher tension is needed upon an incision, sutures may minimize dehiscence. The authors pointed out that there is a need for more well designed randomized controlled trials comparing tissue adhesives and alternative methods of closure. Finally, these trials should include patients whose health may

interfere with wound healing and surgical sites of high tension.

References

1. Manjo G. *The Healing Hand, Man and Wound in the Ancient World*. Cambridge, Harvard University Press, 1977, p. 14.
2. Robicsek F. The birth of the surgical stapler. *Surg Gynecol Obstet*. 1980; 150:579-83.
3. Takaro T. *Institute for Experimental Surgical Instruments in Moscow*. Science. 1963; 142:195-9.
4. Steichen FM, Ravitch MM. Mechanical sutures in surgery. *Br J Surg*. 1973; 60:191-7.
5. Thompson DP, Ashley FL. Use of the stapler in skin closure. *Am J Surg*. 1976; 132:136-7.
6. Keshishian JM. Surgeons find Proximate stapler fast, simple closing device. *Contemp Surg*. 1978; 13:9-16.
7. Meagher SW. Human factors engineering: A primer for the surgeon's participation in industrial injury prevention. *Contemp Orthop*. 1984; 8: 73-80.
8. Comaish S, Bottoms E. The skin and friction: deviation from Amonton's laws, and effects of hydration and lubrication. *Br J Dermatol*. 1971; 84:37-43.
9. Naylor PFD. The skin surface and friction. *Br J Dermatol*. 1955; 67:239-48.
10. Stillman RM, Marino CA, Seilgman SJ. Skin staples in potentially contaminated wounds. *Arch Surg*. 1984; 119:821-2.
11. Edlich RF, Becker DG, Thacker JG, Rodeheaver GT. Scientific basis for selecting staple and tape skin closures. *Clin Plast Surg*. 1990; 17:571-81.
12. Jones KC, Himel HN, Towler MA, Thacker JG, Edlich RF. New advances in automatic disposable rotating cartridge skin staplers. *Burns*. 1993; 19:159-65.
13. Jewell ML, Sato R, Rahija R. A comparison of wound healing in wounds closed with staples versus skin sutures. *Contemp Surg*. 1983; 22:29-32.
14. Johnson A, Rodeheaver GT, Durand LS, Edgerton MT, Edlich RF. Automatic disposable stapling devices for wound closure. *Ann Emerg Med*. 1981; 10:631-5.
15. Roth FH, Windle BH. Staple versus suture closure of skin in a pig model. *Can J Surg*. 1988; 31:19-20.
16. George TK, Simpson DC. Skin wound closure with staples in the accident and emergency department. *J R Coll Surg Edinb*. 1985; 30:54-6.
17. MacGregor FB, McCombe AW, King PM, Macleod DA. Skin stapling of wounds in the accident department. *Injury*. 1989; 20:347-8.
18. Kanegaye JT, Vance CW, Chan L, Schonfeld N. Comparison of skin stapling devices and standard sutures for pediatric scalp lacerations: a randomized study of cost and time benefits. *J Pediatr*. 1997; 130:808-13.

19. Bennet RG. Selection of wound closure materials. *J Am Acad Dermatol.* 1988; 18:619-37.
20. Edlich RF, Thacker JG, Silloway KA, Morgan RC, Rodeheaver GT. Scientific basis of skin staple closure. In: *Advances in Plastic and Reconstructive Surgery*, M.B. Habal (ed). Chicago, IL, Yearbook Medical Publishers, 1987, pp. 233-271.
21. Orlinsky M, Goldberg RM, Chan L, Puertos A, Slajer HL. Cost analysis of stapling versus suturing for skin closure. *Am J Emerg Med.* 1995; 13:77-81.
22. Pineros-Fernandez A, Salopek SL, Rodeheaver PF, Drake DB, Edlich RF, Rodeheaver GT. A revolutionary advance in skin closure compared to current methods. *J Long Term Eff Med Implants.* 2006;16(1):19-27.
23. Cross KJ, Teo EH, Wong SL, Lambe JS, Rohde CH, Grant RT, Ascherman JA. The absorbable dermal staple device: a faster, more cost-effective method for incisional closure. *Plast Reconstruct Surg J.* 2009;124:156-62.
24. Qureshi A, Drew PJ, Duthie GS, Roberts AC, Monson JR. n-Butyl cyanoacrylate adhesive for skin closure of abdominal wounds: preliminary results. *Ann R Coll Surg Engl.* 1997; 79:414-5.
25. Amiel GE, Sukhotnik I, Kawar B, Siplovich L. Use of N-butyl-2-cyanoacrylate in elective surgical incisions--long-term outcomes. *J Am Coll Surg.* 1999; 189:21-5.
26. Farouk R, Drew PJ, Qureshi A, Roberts AC, Duthie GS, Monson JR. Preliminary experience with butyl-2-cyanoacrylate adhesive in tension-free inguinal hernia repair. *Br J Surg.* 1996; 83:1100.
27. Quinn J, Maw J, Ramotar K, Wenckebach G, Wells G. Octylcyanoacrylate tissue adhesive versus suture wound repair in a contaminated wound model. *Surgery.* 1997; 122:69-72.
28. Doraiswamy NV, Baig H, Hammett S, Hutton M. Which tissue adhesive for wounds? *Injury.* 2003; 34:564-7.
29. Pelissier P, Casoli V, Le Bail B, Martin D, Baudet J. Internal use of n-butyl 2-cyanoacrylate (Indermil®) for wound closure: An experimental study. *Plast Reconstruct Surg.* 2001; 108:1661-6.
30. Sinha S, Naik M, Wright V, Timmons J, Campbell AC. A single line, prospective, randomized trial comparing n-butyl, 2-cyanoacrylate tissue adhesive (Indermil®) and sutures for skin closure in hand surgery. *J Hand Surg.* 2001; 26:264-5.
31. Osmond MH, Klassen TP, Quinn JB. Economic comparison of tissue adhesive and suturing in the repair of pediatric facial lacerations. *J Pediatr.* 1995; 126:892-5.
32. Coulthard P, Esposito M, Worthington HV, van der Elst M, van Waes OJ, Darcey J. Tissue adhesives for closure of surgical incisions. *Cochrane Database Syst Rev.* 2010 May 12; 5:CD004287.

Wound Closure Sutures and Needles: A New Perspective

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Ideally, the choice of the suture material should be based on the biological interaction of the materials employed, the tissue configuration, and the biomechanical properties of the wound. Measurements of the *in vivo* degradation of sutures separate them into two general classes: absorbable and nonabsorbable sutures. The nonabsorbable sutures and absorbable sutures are classified according to their origin. When considering an absorbable suture's tensile strength *in vivo*, we recommend that the manufacturer provides specific recommendations of its holding strength, rather than the percentage retained of its initial tensile strength. The newest advance in nonabsorbable sutures is polybutester suture, which is a block copolymer that contains butylene terephthalate (84%) and polytetramethylene ether glycol terephthalate (16%). The expanded polytetrafluoroethylene (ePTFE) suture has been expanded to produce a porous microstructure that is approximately 50% air by volume. The clinical performance of polybutester suture has been enhanced by coating its surface with a unique absorbable polymer. A search for a synthetic substitute for absorbable collagen sutures led to the development of the POLYSORB™ sutures that can reliably approximate tissues with a low risk for infection. The latest innovation in the development of monofilament absorbable sutures has been in the rapidly absorbing CAPROSYN™ suture. A new high-nickel stainless steel, SURGALLOY™, has been used recently to manufacture surgical needles. Biomechanical performance studies of cutting edge needles made of S45500 stainless steel alloy and SURGALLOY™ stainless steel demonstrated that needles made of SURGALLOY™ had superior performance characteristics over those made of S45500.

KEY WORDS: polybutester suture, Polysorb™, Caprosyn™, Surgalloy™ needle

Introduction

There are several different suture materials and needles that provide an accurate and secure approximation of the wound edges. Ideally, the choice of the suture material should be based on the biological interaction of the materials employed, the tissue configuration, and the biomechanical properties of the wound. The tissue should be held in apposition until the tensile strength of the wound is sufficient to withstand stress. A common theme of the many reported investigations is that all biomaterials placed within the tissue damage the host defenses and invite infection. Because surgical needles have a proven role in spreading deadly bloodborne viral infection, the surgeon must select surgical gloves that reduce the risk of accidental injuries during surgery.¹ To protect surgeons and operating room personnel from deadly bloodborne viral infections occurring after glove puncture, we recommend that all operating room personnel wear double-glove hole indication systems that reliably identify glove holes in the outer glove.

Surgical Sutures

Important considerations in wound closure are the type of suture, the tying technique, and the configuration of the suture loops. Selection of a surgical suture material is based on its biologic interaction with the wound and its mechanical performance *in vivo* and *in vitro*. Measurements of the *in vivo* degradation of sutures separate them into two general classes.² Sutures that undergo rapid degradation in tissues, losing their tensile strength within 60 days, are considered absorbable sutures. Those that maintain their tensile strength for longer than 60 days are nonabsorbable sutures. This terminology is somewhat misleading because even some nonabsorbable sutures (ie, silk, cotton and nylon) lose some tensile strength during this 60-day interval. Postlethwait measured the tensile strength of implanted nonabsorbable sutures during a period of two years.³ Silk lost approximately 50% of its tensile strength in one year and had no strength at the end of two years. Cotton lost 50% of its strength in six months, but still had 30% to 40% of its original strength at the end of two years. Nylon lost approximately 25% of its original strength throughout the two-year observation period.

Nonabsorbable Surgical Sutures

The nonabsorbable sutures can be classified according to their origin. Nonabsorbable sutures made from natural fibers are silk sutures. Silk sutures are nonabsorbable, sterile, non-mutagenic surgical sutures composed of natural proteinaceous silk fibers called fibroin. This protein is derived from the domesticated silkworm species *Bombyx mori* of the family *bombycidae*. The silk fibers are treated to remove the naturally-occurring sericin gum, and braided sutures are available coated uniformly with a special wax mixture to reduce capillarity and to increase surface lubricity, which enhances handling characteristics, ease of passage through tissue, and knot rundown properties. Silk sutures are available colored black with Logwood extract.

Metallic sutures are derived from stainless steel. Modern chemistry has developed a variety of synthetic fibers from polyamides (nylon), polyesters (Dacron[®]), polyolefins (polyethylene, polypropylene), polytetrafluoroethylene, to polybutester.

Polypropylene is a linear hydrocarbon polymer that consists of a strand of polypropylene, a synthetic linear polyolefin. All polypropylenes begin with a base resin and then go through the following steps: extrusion, drawing, relaxation, and annealing. Each step in the process will influence the ultimate biomechanical performance of the suture. Biomechanical studies demonstrate that the manufacturing process (ie, annealing, relaxation) can dramatically influence the surface characteristics without altering its strength. Changes in the surface characteristics can facilitate knot construction of the suture. Polypropylene sutures that have a low coefficient of friction will facilitate knot rundown and suture passage through the tissue. A new polypropylene suture has been developed that has increased resistance to fraying during knot rundown, especially with smaller diameter sutures. Polypropylene sutures are extremely inert in tissue and have been found to retain tensile strength in tissues for a period as long as two years. Polypropylene sutures are widely used in plastic, cardiovascular, general, and orthopedic surgery. They exhibit a lower drag coefficient in tissue than nylon sutures, making them ideal for use in continuous dermal and percutaneous suture closure.

Nylon is composed of the long-chain polyamide polymers. While they have a high tensile strength and low tissue reactivity, they degrade *in vivo* at a rate

of about 12.5% per year by hydrolysis. The pliability characteristics of these sutures permit good handling. Because nylon sutures are more pliable and easier to handle than polypropylene sutures, they are favored for the construction of interrupted percutaneous suture closures. However, polypropylene sutures encounter lower drag forces in tissue than nylon sutures, accounting for their frequent use in continuous dermal and percutaneous suture closure. Nylon sutures are also available in a braided construction. These braided nylon sutures are relatively inert in tissue and possess the same handling and knot construction characteristics as the natural fiber, silk sutures.

Polyester sutures are comprised of fibers of polyethylene terephthalate, a synthetic linear polyester derived from the reaction of a glycol and a dibasic acid. Polyester sutures were the first synthetic braided suture material shown to last indefinitely in tissues. Their acceptance in surgery was initially limited because the suture had a high coefficient of friction that interfered with passage through tissue and with the construction of a knot. When the sutures were coated with a lubricant, polyester sutures gained wide acceptance in surgery. This coating markedly reduced the suture's coefficient of friction, thereby facilitating knot construction and passage through tissue. The polyester sutures are coated with either silicone, polybutylene adipate, or teflon.

The polybutester suture (Novafil™, Covidien Inc., Mansfield, MA) is a block copolymer that contains butylene terephthalate (84%) and polytetramethylene ether glycol terephthalate (16%). Polybutester suture has unique performance characteristics that may be advantageous for wound closure.⁴ This monofilament synthetic nonabsorbable suture exhibits distinct differences in elongation compared with other sutures. With the polybutester suture, low forces yield significantly greater elongation than that of the other sutures. In addition, its elasticity is superior to that of other sutures, allowing the suture to return to its original length once the load is removed. In a study by Trimbos et al., they compared the cosmetic outcome of lower midline laparotomy scars using either nylon or polybutester suture for skin closure.⁵ A randomized clinical trial compared polybutester skin suture with that of nylon for lower midline laparotomy wounds in 50 women undergoing gynecologic surgery. Scar hypertrophy, scar width, scar color, the presence of cross-hatching marks, and a total score was assessed in all patients at eighteen months fol-

lowing surgery and compared by nonparametric statistical tests. The wounds closed with polybutester suture were significantly less hypertrophic than those closed with nylon. Regardless of the suture material used, the lower part of the laparotomy scar showed an inferior cosmetic result compared with the upper part underneath the umbilicus for scar hypertrophy, scar width, and the total scar score. The surgeons concluded that polybutester skin suture diminished the risk of hypertrophic scar formation because of its special properties allowing it to adapt to changing tensions in the wound. Increased closure tension of the skin in the midline region above the pubic bone may be caused by a relative immobility of the skin. In 1997, Pinheiro et al. compared the performance of polybutester sutures to that of nylon sutures in 70 male and female rats in which they examined the clinical response of the skin in abdominal wall muscle to the use of these sutures.⁶ Under general anesthesia, standard wounds were created in the dorsum and abdomen of the animals and subjected to suture closure with either polybutester, or nylon. The animals were sacrificed immediately, and at 12, 24, and 72 hours, and at four, five and seven days to evaluate the impact of the sutures on the wounds. Pinheiro et al. found that polybutester suture has some advantages, such as strength, lack of package memory, elasticity, and flexibility, which made suturing quicker and easier. They concluded that polybutester can be used safely on skin and mucosal wounds because it is less irritating to tissues than nylon.

The expanded polytetrafluoroethylene (ePTFE) suture has been expanded to produce a porous microstructure that is approximately 50% air by volume.⁷ The porous nature of the suture allows tissue ingrowth into the suture. The ePTFE suture has some novel performance characteristics that are distinct from those of other monofilament nonabsorbable sutures. ePTFE is greater than 100 times more supple than any monofilament suture, without evidence of plastic memory. In addition, the rate of creep (suture elongation that occurs when a suture is subjected to constant load for an extended period) encountered in the ePTFE suture is significantly less than that in the polypropylene suture. These unique features of the ePTFE suture must be weighed against other important considerations. First, the breaking strength of an unknotted and knotted ePTFE suture is significantly less than that of either the polypropylene or polybutester sutures. For either the polybutester or

polypropylene sutures, three throws are required to form secure square (1=1=1) knots. In contrast, knot security for a square ePTFE knot is accomplished with seven (1=1=1=1=1=1=1) throws.

The clinical performance of polybutester suture has been enhanced by coating its surface with a unique absorbable polymer (Vascufil™, Covidien Inc., Mansfield, MA).⁸ The coating is a Polytribolate™ polymer that is composed of three compounds: glycolide, epsilon-caprolactone, and poloxamer 188. Coating the polybutester suture markedly reduces its drag forces in musculoaponeurotic, colonic, and vascular tissues. Knot security with the coated polybutester suture was achieved with only one more throw than with comparably sized, uncoated polybutester sutures. On the basis of the results of this investigation, coating the polybutester suture represents another major advance in surgical suture performance.

Only nylon and stainless steel sutures are available both as a monofilament and as a multifilament suture. Monofilament stainless steel is manufactured as different diameter single strands of stainless steel. Multifilament stainless steel sutures are formed by winding one filament around another, forming a twisted suture. Long continuous strands of stainless steel are twisted together to form different gauge sutures. Intertwining three or more filaments forms the other multifilament sutures. Several very fine silk fibers are twisted together to form yarns, which are then braided. The number of silk fibers used regulates the suture gauge. A large gauge suture can be made with braids of synthetic filaments by either increasing the number of filaments, or enhancing the size of the filaments.

The ultimate performance of the new cardiovascular sutures and needles must not only be considered as separate entities, but as a complete product with the suture attached to the needle. The introduction and wide acceptance of ePTFE grafts has focused considerable attention on the bleeding that occurs during vascular anastomosis. One of the characteristics of the material is that a needle hole placed in this graft remains approximately the same size as the needle. Needle-hole bleeding is due to the disparity between the diameter of the needle making the hole and the diameter of the suture filling it. With vascular surgical monofilament sutures that have a needle to suture diameter of 2:1, the difference between the sizes of the needles and sutures leaves an unfilled space at each suture hole through which bleeding

occurs. To resolve this problem of bleeding through the holes in the ePTFE grafts, a cardiovascular suture made of ePTFE was developed that can be swaged to a taper point needle that closely approximates its suture diameter, having a needle to suture diameter ratio that approaches 1:1. This 1:1 ratio is allowed because of the porous microstructure of the ePTFE monofilament suture.⁹ Laboratory testing has demonstrated that sutures with a needle to suture ratio of approximately 1:1 encountered less needle hole leakage than sutures with a needle to suture ratio of 2:1. When evaluated with ePTFE graft containing blood maintained at a constant pressure (80 mm Hg), negligible needle hole bleeding was encountered following puncture by a needle with its attached ePTFE suture.¹⁰ A new vascular suture has been designed recently whose diameter also approximates that of its needle diameter, having a needle to suture ratio of 1:1. This vascular suture is a monofilament, polypropylene suture that has been extruded to produce a tapered swage end, which is significantly smaller than that of the remainder of the suture. This tapered suture configuration allows it to be channel swaged to smaller diameter needles, yielding a needle to suture ratio that approaches 1:1.

Insight into the clinical significance of this needle hole bleeding can be gained from the results of experimental studies in animals. Miller et al. recorded the volume of canine anastomotic bleeding in a series of end-to-end, ePTFE graft to ePTFE graft anastomoses made by sutures with different needle to suture diameter ratios.¹¹ They concluded that sutures with a needle to suture ratio of 1:1 were clinically beneficial, caused reduced blood loss, and limited the time spent in surgery, regardless if ePTFE or polypropylene sutures were used. In contrast, sutures with a needle to suture ratio of 2:1 dramatically increased anastomotic bleeding in ePTFE grafts. With the advent of ePTFE grafts with exterior ePTFE yarn wrap, bleeding around suture holes is a less important consideration.

These unique features of the ePTFE sutures must be weighed against other important features. First, the breaking strength for a knotted and unknotted ePTFE suture is approximately one half that of the polypropylene suture. It is also noteworthy that knot construction in an ePTFE suture did not diminish its breaking strength. This maintenance of breaking strength of the ePTFE suture has also been demonstrated by Miller et al.¹¹ In contrast, the breaking strength of polypropylene sutures as well as

other sutures tested was decreased by knot construction.¹² The degree of elongation of the unknotted ePTFE and polypropylene sutures before breakage was remarkably similar, and was not influenced by immersion in 0.9% saline solution. After elongation at the different percent extension that did not lead to breakage, the degree of elasticity of the polypropylene sutures, as measured by percent work recovery, was superior to that of ePTFE sutures.

Absorbable Surgical Sutures

The absorbable surgical sutures are made from either collagen, or synthetic polymers. The collagen sutures are derived from the submucosal layer of ovine small intestine or the serosal layer of bovine small intestine (gut). This collagenous tissue is treated with an aldehyde solution, which cross-links and strengthens the suture and makes it more resistant to enzymatic degradation. Suture materials treated in this way are called plain gut. If the suture is additionally treated with chromium trioxide, it becomes chromic gut, which is more highly cross-linked than plain gut and more resistant to absorption. When this treatment of collagen sutures is limited, the result is a special form of chromic gut, mild gut, which is more susceptible to tissue absorption. The plain gut, mild gut and chromic gut sutures are composed of several plies that have been twisted slightly, machine ground, and polished, yielding a relatively smooth surface that is monofilament-like in appearance. Salthouse and colleagues demonstrated that the mechanism by which gut reabsorbs is the result of sequential attacks by lysosomal enzymes.¹³ In most locations, this degradation is started by acid phosphatase, with leucine aminopeptidase playing a more important role later in the absorption period. Collagenase is also thought to contribute to the enzymatic degradation of these collagen sutures.

The type of gut being used determines the rate of absorption of surgical gut. Plain gut is rapidly absorbed. Its tensile strength is maintained for only seven to ten days postimplantation and absorption is complete within 70 days. Mild chromic gut has had a limited exposure to chromium trioxide to accelerate tensile strength loss and absorption. This fast absorbing surgical gut is used primarily for ophthalmic and cuticular applications where sutures are required for only five to seven days. The tensile strength of chromic gut may be retained for 10 to 14 days.

Natural fiber absorbable sutures have several distinct disadvantages. First, these natural fiber absorbable sutures have a tendency to fray during knot construction. Second, there is considerably more variability in their retention of tensile strength than is found with the synthetic absorbable sutures. A search for a synthetic substitute for collagen sutures began in the 1960s. Soon procedures were perfected for the synthesis of high molecular weight polyglycolic acid, which led to the development of the polyglycolic acid sutures.¹⁴ These sutures are produced from the homopolymer, polyglycolic acid. Because of the inherent rigidity of this homopolymer, monofilament sutures produced from polyglycolic acid sutures are too stiff for surgical use. This homopolymer can be used as a monofilament suture only in the finest size. Consequently, this high molecular weight homopolymer is extruded into thin filaments and braided.¹⁴ The thin filaments of polyglycolic acid sutures are coated with POLYCAPROLATE™, a copolymer of glycolide and epsilon-caprolactone, to reduce the coefficient of friction encountered in knot construction (Dexon™ II, Covidien Inc., Mansfield, MA). The polyglycolic acid sutures degrade in an aqueous environment through hydrolysis of the ester linkage.

Copolymers of glycolide and lactide were then synthesized to produce a LACTOMER™ copolymer that is used to produce a new braided absorbable suture, POLYSORB™, Covidien Inc., Mansfield, MA). The glycolide and lactide behaved differently when exposed to tissue hydrolysis. Glycolide provides for high initial tensile strength, but hydrolyses rapidly in tissue.¹⁴ Lactide has a slower and controlled rate of hydrolysis, or tensile strength loss, and provides for prolonged tensile strength in tissue.¹⁶ The LACTOMER™ copolymer consists of glycolide and lactide in a 9:1 ratio.

The handling characteristics of the POLYSORB™ sutures were found to be superior to those of the Polyglactin 910™ suture.¹⁵ Using comparable knot construction and suture sizes, the knot breaking strength for POLYSORB™ sutures was significantly greater than that encountered by Polyglactin 910™ sutures. In addition, the mean maximum knot rundown force encountered with the POLYSORB™ sutures was significantly lower than that noted with the Polyglactin 910™ sutures, facilitating knot construction.

The surfaces of the POLYSORB™ sutures have been coated to decrease their coefficient of friction.¹⁵ The new POLYSORB™ suture is coated with an

absorbable mixture of caprolactone/glycolide copolymer and calcium stearoyl lactylate. At 14 days post-implantation, nearly 80% of the USP (United States Pharmacopoeia) tensile strength of these braided sutures remains. Approximately 30% of their USP tensile strength is retained at 21 days. Absorption is essentially complete between days 56 and 70.

Drake et al. recently studied the determinants of suture extrusion following subcuticular closure by synthetic braided absorbable sutures in dermal skin wounds.¹⁶ Miniature swine were used to develop a model for studying suture extrusion. Standard, full-thickness skin incisions were made on each leg and the abdomen. The wounds were closed with either size 4-0 POLYSORB™ or COATED VICRYL™ (Ethicon, Inc., Somerville, New Jersey) sutures. Each incision was closed with five interrupted, subcuticular, vertical loops secured with a surgeon's knot. The loops were secured with 3-throw knots in one pig, 4-throw knots in the second pig, and 5-throw knots in the third pig. The swine model reproduced the human clinical experience: suture extrusion, wound dehiscence, stitch abscess, and granuloma formation were all observed. The cumulative incidence of suture extrusion over five weeks ranged from 10% to 33%. COATED VICRYL™ sutures had a higher mean cumulative incidence of suture extrusion than that of POLYSORB™ sutures (31% vs. 19%). With POLYSORB™ sutures, the 5-throw surgeon's knots had a higher cumulative incidence of suture extrusion than the 3-throw or 4-throw surgeon's knot square, 30% vs. 17% and 10%, respectively. This swine model offers an opportunity to study the parameters that influence suture extrusion. Because the volume of suture material in the wound is obviously a critical determinant of suture extrusion, it is imperative that the surgeon construct a knot that fails by breakage, rather than by slippage, with the least number of throws. Because both braided absorbable suture materials are constructed with a secure surgical knot that fails only by breakage rather than slippage with a 3-throw surgeon's knot square ($2 = 1 = 1$), the construction of additional throws with these sutures does not enhance the suture holding capacity, but plays a key factor in precipitating suture extrusion. Finally, it is important to emphasize that the surgeon must always construct symmetrical surgical knots for dermal subcuticular skin closure in which the constructed knot is always positioned perpendicular to the linear wound incision. Asymmetrical knot construction for

dermal wound closure becomes an obvious invitation for suture extrusion.

When coated polyglactin 910 sutures were treated with a pure form of triclosan, this suture inhibited the growth of bacteria.¹⁷ The addition of the triclosan to coated polyglactin 910 sutures did not affect physical handling properties and performance characteristics. In addition, this suture did not appear to impair wound healing.¹⁸ Finally, the presence of the antibiotic did not influence the absorption of the polyglactin 910 braided sutures.

A monofilament absorbable suture, polydioxanone, has been prepared from the polyester, poly(*p*-dioxanone).¹⁹ The results of implantation studies of polydioxanone monofilament sutures in animals indicate that approximately 70% of its original strength remains two weeks after implantation. At four weeks postimplantation, approximately 50% of its original strength is retained, and at six weeks, approximately 25% of the original strength is retained. Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th postimplantation day. Absorption is essentially complete within six months.

Another monofilament absorbable suture has been developed using trimethylene carbonate.²⁰ Glycolide trimethylene carbonate is a linear copolymer made by reacting trimethylene carbonate and glycolide with diethylene glycol as an initiator and stannous chloride dihydrate as the catalyst. The strength of the monofilament synthetic absorbable suture, glycolide trimethylene carbonate, is maintained *in vivo* much longer than that of the braided synthetic absorbable suture. This monofilament suture retained approximately 50% of its breaking strength after implantation for 28 days, and still retained 25% of its original strength at 42 days. In contrast, braided absorbable sutures retained only 1% to 5% of their strength at 28 days. Absorption of the trimethylene carbonate suture is minimal until about the 60th day postimplantation, and is essentially complete within six months.

A recent innovation in the development of monofilament synthetic absorbable sutures has been the production of Glycomer 631 (Biosyn™, Covidien Inc., Mansfield, MA), a terpolymer composed of glycolide (60%), trimethylene carbonate (26%), and dioxanone (14%). This monofilament suture has many distinct advantages over the braided synthetic absorbable sutures.²⁰ First, this monofilament suture

is significantly stronger than the braided synthetic absorbable suture over four weeks of implantation. It maintains approximately 75% of its USP tensile strength at two weeks and 40% at three weeks post-implant. Absorption is complete between 90 to 110 days. In addition, this monofilament suture potentiates less bacterial infection than does the braided suture. The handling characteristic of this monofilament suture is superior to the braided suture because it encounters lower drag forces in the tissue than does the braided suture.

The latest innovation in the development of monofilament absorbable sutures has been the rapidly absorbing CAPROSYN™ suture (Covidien Inc., Mansfield, MA). CAPROSYN™ monofilament synthetic absorbable sutures are prepared from POLYGLYTON™ 621, a synthetic polyester that is composed of glycolide, caprolactone, trimethylene carbonate, and lactide. Implantation studies in animals indicate that CAPROSYN™ suture retains a minimum of 50% to 60% USP knot strength at five days postimplantation, and a minimum of 20% to 30% of knot strength at 10 days postimplantation. All of its tensile strength is essentially lost by 21 days postimplantation.

Pineros-Fernandez et al. recently have compared the biomechanical performance of CAPROSYN™ suture to that of chromic gut suture.²² The biomechanical performance studies included quantitative measurements of wound security, strength loss, mass loss, potentiation of infection, tissue drag, knot security, knot rundown, as well as suture stiffness. Both CAPROSYN™ and chromic gut sutures provided comparable resistance to wound disruption. Prior to implantation, suture loops of CAPROSYN™ had a significantly greater mean breaking strength than suture loops of chromic gut. Three weeks after implantation of these absorbable suture loops, the sutures had no appreciable strength. The rate of loss of suture mass of these two sutures was similar. As expected, chromic gut sutures potentiated significantly more infection than did the CAPROSYN™ sutures.

The handling properties of the CAPROSYN™ sutures were far superior to those of the chromic gut sutures. The smooth surface of the CAPROSYN™ sutures encountered lower drag forces than did the chromic gut sutures. Furthermore, it was much easier to reposition the CAPROSYN™ knotted sutures than the knotted chromic gut sutures. In the case of chromic gut sutures, it was not possible to reposi-

tion a two-throw granny knot. These biomechanical performance studies demonstrated the superior performance of synthetic CAPROSYN™ sutures compared to chromic gut sutures and provide compelling evidence of why CAPROSYN™ sutures are an excellent alternative to chromic gut sutures.

The direct correlation of molecular weight and breaking strength of the synthetic absorbable sutures with both *in vivo* and *in vitro* incubation implies a similar mechanism of degradation. Because *in vitro* incubation provides only a buffered aqueous environment, the chemical degradation of these sutures appears to be by nonenzymatic hydrolysis of the ester bonds. Hydrolysis would be expected to proceed until small, soluble products are formed, then dissolved, and removed from the implant site. In contrast, the gut or collagen suture, being a proteinaceous substance, is degraded primarily by the action of proteolytic enzymes.

A distinction must be made between the rate of absorption and the rate of tensile strength loss of the suture material. The terms *rate of absorption* and *rate of tensile strength loss* are not interchangeable. Although the rate of absorption is of some importance with regard to late suture complications, such as sinus tracts and granulomas, the rate of tensile strength loss is of much greater importance to the surgeon considering the primary function of the suture, maintaining tissue approximation during healing.

When considering an absorbable suture's tensile strength *in vivo*, we recommend that the manufacturer provide specific measurements of its holding capacity, rather than the percentage retained of its initial tensile strength. The United States Pharmacopoeia (USP) has set tensile strength standards for synthetic absorbable suture material. If the manufacturers were to use these standards to describe maintenance of tensile strength, the surgeon would have a valid clinical perspective to judge suture performance. Some manufacturers persist in reporting maintenance of the tensile strength of their suture in tissue by referring only to the percentage retained of its initial tensile strength, making comparisons between sutures difficult. The need to use USP standards in reporting is particularly important when there are marked differences in the initial tensile strengths of the synthetic sutures. For example, the initial tensile strength of Glycomer 631 is 43% stronger than that of polydioxanone. At two weeks, the Glycomer 631 suture is approximately 30% stronger.

Suture Infection-Potentiating Effect

All sutures damage the local tissue defenses to infection, and several mechanisms are implicated. The trauma of inserting a needle is sufficient to cause an inflammatory response. The surgeon's suturing technique is crucial. Sutures tied too tightly impair tissue defenses and invite infection.²³ Sutures that penetrate the intact skin provide an avenue for wound contamination by means of the perisutural cuff. The presence of the suture material increases the tissue's susceptibility to infection. The magnitude of this local injury to defenses is related to the quantity of suture within the wound (ie, diameter, length) and to the suture's chemical composition.

The infection potentiating effects of suture materials are listed in Table 1.²⁴ For the absorbable sutures, synthetic monofilament sutures elicit the least inflammatory response followed by the multifilament absorbable sutures. All of the synthetic absorbable sutures were less reactive than the natural fiber absorbable sutures. Of the natural fiber absorbable sutures, plain gut was less reactive than chromic gut.

Similarly, the monofilament nonabsorbable sutures were the least reactive of the nonabsorbable sutures, followed by the multifilament synthetic nonabsorbable sutures. Of all sutures, the metallic sutures are the most reactive because of their stiff configuration. Realizing this, the monofilament stainless steel sutures were less reactive than the multifilament stainless steel sutures. The relatively high infection rates encountered with either monofilament or multifilament stainless steel sutures may be the result of their chemical or physical configuration. Stainless steel is not generally as inert as pure polymers and undergoes degradation *in vivo*. In addition, metallic sutures are so stiff that patient movement induces tissue damage and impairs the wound's ability to resist infection.

Sutures made of natural fibers potentiate infection more than any other nonabsorbable sutures; this

correlates with the tissue's reaction to these sutures in clean wounds.²⁴ It would appear from these experimental studies that the use of silk and cotton should be avoided in wounds that have experienced gross bacterial contamination. Furthermore, because the handling characteristics of the highly reactive natural fiber sutures are indistinguishable from those of the less reactive braided nylon sutures, we believe that there is no clinical role for these natural fiber sutures in surgery.

The physical configuration of a suture has a significant role in the development of infection. Using a model similar to that reported by our laboratory, Sharp and colleagues found that the synthetic monofilament sutures were associated with less infection than that encountered with the multifilament synthetic sutures exposed to the same bacterial inocula.²⁵ The superiority of the synthetic absorbable sutures over the naturally occurring gut sutures was also evident with this model.

In general, the techniques of sutural closure of skin can be divided into two types: percutaneous sutures and dermal (subcuticular) sutures. The selection of the technique for closure is influenced by the wound's configuration and biomechanical properties, as well as other special circumstances. Percutaneous sutures of either monofilament nylon or polypropylene are excellent for closure of skin wounds because these suture materials exert the least damage to the wounds' defenses.² Because the magnitude of the suture's damage to the local tissue defenses is related to the quantity of the suture within the wound (ie, diameter, length), we employ the narrowest diameter suture (5-0 or 6-0) whose strength is sufficient to resist disruption of the skin wound. By approximating the middle portion and the bisected portions of the unclosed wound with percutaneous sutures, the least length of suture can be employed in the skin closure. An interrupted dermal suture placed in each quadrant of a wound subjected to strong static and

Table 1. Infection-potentiating Effect of Surgical Suturestm

Absorbable	Non-absorbable
Synthetic Monofilament	Synthetic Monofilament
Synthetic Multifilament	Synthetic Multifilament
Plain gut	Silk = cotton
Chromic gut	

dynamic skin tensions provides sufficient strength to permit early suture removal. Sutural closure of the adipose tissue beneath the skin should be avoided.²⁶ Obliteration of this potential dead space between the cut edge of adipose tissue by even the least reactive suture increases the incidence of infection.

When wounds of different thickness are to be reunited, the needle having passed through one edge of the wound should be drawn out before reentry through the other side of the wound. This maneuver will ensure that the needle will be inserted at comparable levels on each side of the wound. Unless appropriate adjustment of the bite is made on the thinner side, uneven coaptation of the skin will occur resulting in a step-off scar. Grasping or crushing of the skin edges by forceps should be avoided during approximation of the wound.

Dermal (subcuticular) sutures can be used alone or as adjuncts to percutaneous sutures in wounds subjected to strong skin tensions; they serve as an added precaution against disruption of the wound. Dermal sutures are employed as either interrupted or continuous sutures. Some surgeons prefer a synthetic absorbable suture for dermal closure, whereas others favor a synthetic nonabsorbable suture. When continuous nonabsorbable dermal sutures are employed, the wound is additionally supported with interrupted synthetic absorbable dermal sutures. The continuous nonabsorbable dermal suture is removed before the eighth day after wound closure to prevent the development of needle puncture scars.

In special circumstances, percutaneous sutures should be avoided in favor of dermal sutures: (1) infants frightened at the prospect of suture removal, (2) follow-up appointments are difficult to keep, (3) wounds covered by casts, and (4) patients prone to the development of keloids. When dermal closure alone is used, it is advisable to immediately apply tape skin closures to the wound edges to provide a more accurate approximation of the epidermis.

The influence of dermal suture closure on the wound infection rate is a subject of debate. Certainly, dermal suture closure reduces or completely prevents the normal serosanguinous discharge noted on surgical dressings, which therefore may remain in the wound serving as a culture medium for bacteria. In a prospective clinical trial by Foster and colleagues in 127 patients after appendectomy, wound infections were significantly more common after dermal polyglycolic acid sutures than in wounds approximated by

percutaneous interrupted nylon sutures.²⁷ In another clinical study by Hopkinson and Bullen involving 184 patients after appendectomy, the infection rate in wounds after interrupted dermal polypropylene sutures did not differ from that of wounds approximated by continuous dermal polypropylene sutures.²⁸

There is general agreement, however, that wounds subjected to continuous dermal (subcuticular) closure are more resistant to exogenous bacterial contamination than wounds closed by percutaneous sutures.²⁹ The percutaneous suture serves as an avenue for the migration of bacteria from the skin surface into the wound. After infection develops beneath the dermal skin closure, the collecting purulent exudate spreads preferentially between the divided edges of fat rather than penetrating the sutural closure. By the time infection becomes clinically apparent, it has involved the entire extent of the wound. This circumstance is distinct from the localized collections of purulent discharge encountered in infected wounds closed by either interrupted percutaneous sutures or tape. In the latter circumstance, the purulent discharge first exits between the wound edges before spreading between the divided layers of adipose tissue.

Another concern about continuous dermal nonabsorbable sutures is that suture pullout may require considerable force that may break the suture and may be accompanied by patient discomfort. Several technical considerations may facilitate suture pullout.³⁰ First, polypropylene sutures are advocated over other monofilament nonabsorbable sutures because their surface displays the lowest coefficient of friction facilitating suture removal. In addition, continuous dermal polypropylene sutures should be surfaced as a percutaneous loop every 3 cm to allow shorter segments of the suture to be removed. Suture pullout by elastic traction applied over minutes to hours is considerably easier than suture pullout by manual traction over a short time. Despite the immediate aesthetically pleasing appearance of dermal skin closure, it does not improve the cosmetic appearance of the scar.³¹

The type of sutures used to approximate fascia (galea aponeurotica), however, has considerable influence on the width and depth of skin scars. In a study by Nordström and Nordström of a group of patients undergoing scalp excision for correction of androgenic alopecia, polypropylene sutures reduced the postoperative stretching and depth of skin scars more than comparably sized polyglycolic acid sutures.³² Another approach to reducing static skin tensions on the

wound is to undermine its edges before closure. Despite common clinical usage of this technique, there has been only one experimental study that objectively evaluated its effects on wound closure. In this *in vivo* study, McGuire identified the directional orientation of the static skin tensions by observing the oval distortion of 6 mm circular skin biopsy sites in pigs.³³ At each location, the immediate change in the shape of the resulting defect indicated the magnitude and directional properties of the static skin tensions. The direction of the static skin tension lines corresponded to the long axes of the defects. Wounds parallel to these static skin tension lines required less force and work to close initially, retracted less with initial excision, and benefited more from undermining than similar wounds oriented perpendicularly to the static skin tension lines. Because undermining the wound margin decreased the forces required for wound closure, it should limit the width of the ultimate scar. This benefit, however, must be weighed against its potential damage to the skin blood supply, which may limit the host's defenses and invite infection. Consequently, we reserve undermining for wounds that are subjected to strong static and dynamic tensions, with low levels of bacterial contamination, during elective surgical procedures.

Suture Knot Tying

This approach to suturing has contributed to a growing concern that the knot construction employed by many surgeons is not optimal and that they use faulty technique in tying knots, which is the weakest link in a tied surgical suture. When a knotted suture fails to perform its function, the consequences may be disastrous. Massive bleeding may occur when the suture loop surrounding a vessel becomes untied or breaks. Wound dehiscence or incisional hernia may follow knot disruption.

Consequently, the surgeon must develop considerable expertise in tying knots in surgical sutures using either an instrument tie or manual tie techniques. First, the surgeon must have an understanding of the components of a knotted suture loop. Second, he/she must appreciate the mechanical performance of an untied and knotted suture. Important considerations in suture mechanical performance include knot breakage, knot slippage, suture cutting tissue, and mechanical trauma. The surgeon's tying technique remains one of the most important considerations.

Components of a Knotted Suture Loop

The mode of operation of a suture is the creation of a loop of fixed perimeter secured in the geometry by a knot.³⁴ A tied suture has three components. First, the loop created by the knot maintains the approximation of the divided wound edges. Second, the knot is composed of a number of throws snugged against each other. A throw is a wrapping or weaving of two strands. Finally the "ears" act as insurance that the loop will not become untied because of knot slippage. The doctor's side of the knot is defined as the side of the knot with "ears," or the side to which tension is applied during tying. The patient's side is the portion of the knot adjacent to the loop.

Each throw within a knot can be either a single or double throw. A single throw is formed by wrapping the two strands around each other so that the angle of the wrap equals 360° . In a double throw, the free end of a strand is passed twice, instead of once, around the other strand; the angle of this double-wrap throw is 720° . The tying of one or more additional throws completes the knot. The configuration of the knot can be classified into two general types by the relationship between the knot "ears" and the loop. When the right "ear" and loop of the two throws exit on the same side of the knot or parallel to each other, the type of knot is judged to be square (reef). The knot is considered a granny type if the right "ear" and loop exit or cross different sides of the knot. When the knot is constructed by an initial double-wrap throw followed by a single throw, it is called a surgeon's (friction) knot. The configuration of a reversed surgeon's knot is a single throw followed by a double-wrap throw. A knot consisting of two double-wrap throws is appropriately called a double-double.

When forming the first throw of either a square or granny knot, the surgeon is merely wrapping one suture end (360°) around the other, with the suture ends exiting in opposite directions. The surgeon will apply equal and opposing tension to the suture ends in the same planes. The direction of the applied tensions will be determined by the orientation of the suture loop in relation to that of the surgeon's hands. When the surgeon's hands lie on each side and parallel to the suture loop, the surgeon will apply tensions in a direction parallel to his/her forearms. Tension will be applied to the farther suture end in a direction away from the surgeon. Conversely, an equal oppos-

ing force will be applied to the closer suture end in a direction toward the surgeon. After constructing the second throw of these knots, the direction of the suture ends must be reversed, with an accompanying reversal of the position of the surgeon's hand.³⁵ As the surgeon's hands move toward or away from his body, the movements of his right and left hands are in separate and distinct areas that do not cross, permitting continuous visualization of knot construction. With each additional throw, the surgeon must reverse the position of his/her hands.

Orientation of the suture loop in a plane that is perpendicular to that of the surgeon's forearms considerably complicates knot construction. In this circumstance, reversal of the position of the hands occurs in the same area, with crossing and overlapping of the surgeon's hands, temporarily obscuring visualization of knot construction. This circumstance may be encountered when constructing knots in a deep body cavity, which considerably limits changes in hand positions. This relatively cumbersome hand position may interfere with the application of uniform opposing tensions to the suture ends, an invitation to the conversion of a square knot construction to a slip knot.

The granny knot and square knot can become a slip knot by making minor changes in the knot tying technique. Surgeons who do not reverse the position of their hands after forming each throw will construct slip knots. Furthermore, the application of greater tension to one "ear" than the other, encourages construction of slip knots, a practice commonly encountered in tying deep-seated ligatures.³⁶ When the tension is reapplied in equal, and opposing directions, the slip knots can usually be converted into either the square or granny knots.

A simple code has been devised to describe a knot's configuration.³⁷ The number of wraps for each throw is indicated by the appropriate Arabic number. The relationship between each throw being either crossed or parallel is signified by the symbols \times or $=$, respectively. In accordance with this code, the square knot is designated $1=1$, and the granny knot 1×1 . The presence of a slip knot construction is indicated by the letter S. This method of describing knots facilitates their identification and reproduction. It is, for example, perfectly obvious what is meant by $2\times 2\times 2$, without giving the knot a name, and all surgical knots can be defined unequivocally in this international language.

Biomechanical Performance

The mechanical performance of a suture is an important consideration in the selection of a surgical suture and can be measured by reproducible, biomechanical parameters.³⁸ The suture's stiffness reflects its resistance to bending. Its coefficient of friction is a measure of the resistive forces encountered by contact of the surfaces of the suture material during knot construction. Strength is a key performance parameter that indicates the suture's resistance to breakage. The knot breakage load for a secure knot that fails by breakage is a reliable measure of strength. During these tests, forces are applied to the divided ends of the suture loop. As the suture is subjected to stress, it will elongate. The load elongation properties of a suture have important clinical implications. Ideally, the suture should elongate under low loads to accommodate for the developing wound edema, but return to its original length after resolution of the edema. Although it should exhibit an immediate stretch under low loads, it should not elongate any further while continuously maintaining the load, exhibiting a resistance to creep.

These biomechanical parameters play important roles in the clinical performance of the suture. Surgeons consider the handling characteristics of the suture to be one of the most important parameters in their selection of sutures. Surgeons evaluate the handling characteristics of sutures by constructing knots using manual and instrument-tie techniques. The surgeon prefers a suture that permits two-throw knots to be easily advanced to the wound edges, providing a preview of the ultimate apposition of the wound edges. The force required to advance the knot is called knot rundown force. Once meticulous approximation of the wound edges is achieved, the surgeon prefers to add one more throw to the two-throw knot so that it does not fail by slippage.

The magnitude of the knot rundown force is influenced considerably by the configuration of two-throw knots.³⁹ Knot rundown of the surgeon's knot square ($2=1$) generates sufficient forces to break the knot. In contrast, knot rundown of square ($1=1$), granny (1×1), and slip ($S=S$, $S\times S$) knots occurs by slippage. For comparable sutures, the mean knot rundown force for square knots is the greatest, followed by that for the granny (1×1) knots, and then the slip ($S=S$, $S\times S$) knots.

Failure of the knotted suture loop may be the result of either knot slippage or breakage, suture

cutting through tissue, and mechanical crushing of the suture by surgical instruments. Initially, the knotted suture fails by slippage, which results in untying of the knot. All knots slip to some degree, regardless of the type of suture material. When slippage is encountered, the cut ends (“ears”) of the knot must provide the additional material to compensate for the enlarged suture loop. When the amount of knot slippage exceeds the length of the cut “ears,” the throws of the knot become untied. In general, surgeons recommend that the length of the knot “ears” be 3 mm to accommodate for any knot slippage. Dermal sutures are, however, an exception to this rule. Because the “ears” of dermal suture knots may protrude through the divided skin edges, surgeons prefer to cut their dermal suture “ears” as they exit from the knot. It must be emphasized that knot security is achieved in a knot without “ears” with one more throw than in a comparable knot whose “ear” length is 3 mm.

Knot Slippage

Knot slippage is counteracted by the frictional forces of the knots. The degree to which a knot slips can be influenced by a variety of factors including the coefficient of the friction of the suture material, suture diameter, moisture, knot type and final geometry. Knots of the granny type (crossed) usually exhibit more slippage than do knots with a square-type (parallel) construction.

With each additional throw, incrementally greater forces are required for knot untying. After a specified number of throws, failure will occur by knot breakage, after which the knot breakage force will not be enhanced by the addition of more throws. Consequently, these additional throws offer no mechanical advantage and represent more foreign bodies in the wound that damage host defenses and resistance to infection.

The human element in knot tying has considerable influence on the magnitude of knot slippage.³⁵ The amount of tension exerted by the surgeon on the “ears” of the knot significantly alters the degree of slippage. The careless surgeon who applies minimal tension (10% of knot break strength) to the “ears” of the knot constructs knots that fail by slippage. Knot slippage can be minimized by applying more tension (80% of knot break strength) to the “ears” of the knot. Another serious error often made by the inex-

perienced surgeon is not changing the position of his/her hands appropriately during construction of square and/or granny type knots. The resulting knot, a sliding or slip knot, will become untied, regardless of the suture material. The risk of forming a slip knot is greatest when tying one-hand knots and/or with deep seated ligatures.^{39,40}

Knot Breakage

When enough force is applied to the tied suture to result in breakage, the site of disruption of the suture is almost always the knot. The force necessary to break a knotted suture is lower than that required to break an untied suture made of the same material.³⁴ The forces exerted on a tied suture are converted into shear forces by the knot configuration that break the knot. The percentage loss of tensile strength, as a result of tying a secure knot, is least with monofilament and multifilament steel.⁴¹ This relationship between the tensile strength of unknotted and knotted suture, which is designated knot efficiency, is described in the following equation.

$$\text{KNOT EFFICIENCY (\%)} = \frac{\text{tensile strength of a knotted suture}}{\text{tensile strength of unknotted suture}}$$

Regardless of the type of suture material, the efficiency of the knot is enhanced with an increasing number of throws, although only up to a certain limit.

The type of knot configuration that results in a secure knot that fails by breaking varies considerably with different suture material. The magnitude of force necessary to produce knot breakage is influenced by the configuration of the knotted suture loop, type of suture material, and the diameter of the suture.³⁴ The tissue in which the suture is implanted also has considerable influence on the knot strength of suture. In the case of absorbable sutures, a progressive decline in knot breaking strength is noted after tissue implantation. In addition, the magnitude of knot breakage force is significantly influenced by the rate of application of forces to the “ears” of the knot.⁴¹ When a constant force is applied slowly to the knot “ears,” the knot breakage force is significantly greater than that for knots in which the same constant force is applied rapidly to the “ears.” The latter knot loading rate is often referred to as “the jerk at the end of the knot,” especially when the knotted suture breaks.

Suture Cutting Tissue

Suture failure also may occur if the knotted suture loop cuts through the tissue. The type of tissue has considerable influence on the magnitude of force required to tear the suture through the tissue. Howes and Harvey reported that the forces required to tear gut sutures through canine fascia were the greatest followed by muscle, peritoneum and then fat.⁴⁰ Using cadaver specimens six to 93 days after death, Tera and Åberg measured the magnitude of forces required for suture to tear through excised musculoaponeurotic layers of laparotomy incisions.⁴² The rationale for this study was that the forces required to tear sutures through a musculoaponeurotic layer would provide a basis for the choice of a suture whose strength is at least as strong as the forces required to tear the suture through the tissue. When the suture was passed lateral to the transition between the linea alba and the rectus sheath, the force required to tear the suture through the tissue was greater than that for any other musculoaponeurotic layer tested; the paramedian incision required the lowest forces to pull sutures through its sheaths. When they recorded the forces needed for sutures to tear through structures involved in the repair of inguinal hernia, the structures making up the conjoined tendon and Cooper's ligament were the strongest and exhibited twice the resistance to suture tearing than those of the other structure.

As expected, the force required for sutures to tear through tissue changes during healing. Åberg reported that the forces needed for sutures to tear through the aponeurotic muscle layer reduced significantly during the first week of healing.⁴³ When the wound edges were approximated by sutures tied tightly around this aponeurotic muscle layer, the reduction in force needed for the suture to pull through this tissue persisted for two weeks.

Mechanical Trauma

Mechanical trauma to the suture by surgical instruments can also result in suture failure. Nichols et al. cautioned surgeons about the handling of sutures by surgical instruments.⁴⁴ They indicated that either the application of clamps and forceps to sutures or rough handling of sutures could damage and weaken them. Stamp et al. incriminated the teeth in the needle holder jaws as important causal factors of sutural damage.⁴⁵ Compression of sutures between the

needle holder jaws with teeth produced morphologic changes in sutures that resulted in a marked reduction in the suture breaking strength. Similarly, the sharp edges of needle holder jaws without teeth can even crush the suture and thereby decrease its strength.⁴⁶ Finally, application of large compressive loads by pinching polypropylene sutures with DeBakey forceps decreased the strength of the suture.⁴⁷

Tying Technique

The surgeon may use an individual ligature ("free tie") or a suture that is attached to a needle or ligature reel. The length of a free tie or suture attached to a needle is usually 18 inches. The longest strands of suture material are available on a reel or spool. When the suture is attached to a needle or reel, there is a free end and a fixed end; the fixed end is attached to either the needle or reel. The first throw of a knot is accomplished by wrapping the free end either once or twice (surgeon's) around the fixed end. During practice, clamp one end of the suture with an instrument that serves to represent either the needle or the reel, which is the fixed end of the suture.

Formation of each throw of a knot is accomplished in three steps. The first step is the formation of a suture loop. In the second step, the free suture end is passed through the suture loop to create a throw. The final step is to advance the throw to the wound surface. For the first throw of a square, granny, and surgeon's knot square, tension is applied to the suture ends in opposite directions. With each additional throw, the direction in which tension is applied to the suture ends is reversed. The surgeon should construct a knot by carefully snugging each throw tightly against each other. The rate of applying tension to each throw should be relatively slow.

For either the square knot or surgeon's knot square, the direction in which the free suture end is passed through the loop will be reversed for each additional throw. If the free suture end is passed down through the first suture loop, it must be passed up through the next suture loop. Reversal of the direction of passage of the free suture end through the loop does not alter either the knot's mechanical performance or its configuration. It simply reverses the presentation of the knot. For granny knots, the direction in which the free suture end is passed through the loop is the same for each additional throw.

During surgery, knot construction involves two distinct steps. The purpose of the first step is to secure precise approximation of the wound edges by advancing either a one-throw or a two-throw knot to the wound surface. Once the throw or throws contact the wound, the surgeon will have a preview of the ultimate apposition of the wound edges. Ideally, the knotted suture loop should reapproximate the divided wound edges without strangulating the tissue encircled by the suture loop. If there is some separation of the wound edges, the one-throw or two-throw knot can be advanced to reduce the size of the suture loop and thereby bring the wound edges closer together.

When the surgeon forms a double-wrap throw, the first throw of the surgeon's knot square (2=1) can maintain apposition of the wound edges by "locking" or temporarily securing it in place by reversing the direction of pull on its "ears." The "locked" double throw is not a reliable means of maintaining wound apposition because any tension applied to the "ears" from the patient's side of the knot will unlock the knot. The addition of the second throw to the surgeon's knot square (2=1) will provide additional resistance to wound disruption, but this knot will not advance by slippage, limiting the surgeon's ability to secure meticulous coaptation of the wound edges.³⁶

In contrast, two-throw square (1=1) or granny (1x1) knots can be advanced to the wound surface to secure precise wound edge apposition. These two-throw square (1=1) or granny (1x1) knots can be easily converted into their respective slip knots by applying tension to only one "ear" in a direction that is perpendicular to that of the tissue surface. Surgeons may inadvertently construct slip knots when tying knots with one-hand technique or forming knots in deep cavities.³⁹ The risk of tying slip knots can be obviated by applying tensions to both "ears" in horizontal planes parallel to the tissue surface.

The second step in knot construction is the addition of a sufficient number of throws to the knot so that it does not fail by slippage. The magnitude of knot breakage force is always greater than that for knot slippage force of a comparable suture, ensuring optimal protection against wound dehiscence.

Instrument Tie

Knot construction can be accomplished by either an instrument or hand tie.⁴⁶ An instrument tie occurs by the formation of a suture loop over an instru-

ment, usually a needle holder. The right hand holds the needle holder, while the left hand loops the fixed suture end around the instrument. The position of the instrument in relation to the suture ends during knot construction will determine the type of knot. When the instrument is placed above the fixed suture end during the first and second throws, a square-type knot will develop. In contrast, a granny-type knot will first result when the instrument is placed above the fixed suture end for the first throw and then below the fixed suture end for the second throw. By repeating this positioning, the instrument tie is a reliable and easy method to produce multiple throw granny knots (1x1x1), a circumstance not encountered in hand ties. Granny knots with more than two throws cannot be constructed by either the one-hand or two-hand technique, without releasing hold of both suture ends.

Instrument tying is accomplished primarily by the surgeon's left hand, which holds the fixed suture end. Initially, the length of the fixed suture end held by the left hand is long (17 in), making it difficult to form knots without injuring the attending assistant. This assault can be avoided by shortening the length of the fixed suture end held by the left hand. Preferably, the fixed suture end should be coiled into loops, which are held between the tips of the thumb and index finger. This maneuver is accomplished by first grasping the fixed suture end with the small and ring fingers, while it is being pinched between the tips of the index finger and thumb. By pronating the wrist, a loop forms around the grasped fingers and the top of the loop must again be grasped between the tips of the thumb and index fingers. The small and ring fingers are then withdrawn from the loop before coiling more suture. The grasped suture can be easily lengthened by releasing the coils held between the tips of the thumb and the index finger.

When tying knots with an instrument, it is difficult to apply continuous tension to the suture ends. Consequently, widening of the suture loop due to slippage is frequently encountered in wounds subjected to strong tensions. This technique, however, is ideally suited for closing a wound that is subjected to weak tensions. In this circumstance, instrument ties can be accomplished more rapidly and accurately than hand ties, while conserving considerably more suture. By using this technique, the parsimonious surgeon can complete 10 interrupted suture loops for one suture measuring 18 inches in length. This feat would be impossible if the knots had been tied by hand.

The value of instrument ties has become readily apparent in special situations in which hand ties are impractical or impossible. In microsurgical procedures, an instrument tie provides the most reliable and easiest method of knot construction. When employing suture in the recesses of the body (eg, mouth, vagina, etc.) or during endoscopic surgery, instruments can also form knots in sites to which the hand could never gain access.

Hand Tie

Hand tying of knots can be accomplished by either the two-hand or one-hand technique. Each technique has distinct advantages as well as drawbacks. The two-hand technique of knot tying is easier to learn than the one-hand. An additional advantage of the two-hand tie is that the surgeon can apply continuous tension to the suture ends until a secure knot is formed. With the one-hand method, it is often difficult to maintain tension on the suture ends during the formation of the knot and slippage of the first or second throws will be encountered, especially by the inexperienced surgeon. When the surgeon attempts to shorten the resultant enlarged loop by advancing the knot, breakage of the suture may occur, requiring passage of another suture through the once punctured tissue. The student of surgery should master first the construction of square-type knots because knot security can usually be achieved with fewer throws than the granny-type knots.⁴⁷ The additional foreign bodies required to form a secure granny knot, predisposes the wound to the development of infection.

The hand-tying techniques illustrated in this manual are those used by right-handed individuals. Using the two-hand technique, he/she constructs the knot predominantly with his/her left hand, which forms a suture loop through which the free suture end is passed. The left hand continually holds the suture end until knot construction is complete. In contrast, the right hand merely holds, releases, and regrasps the free suture end. If the surgeon inadvertently manipulates the fixed suture end with his/her right hand, he/she will be passing either the needle or reel through the formed loop. The latter case is an invitation to needle glove puncture.

Many right-handed surgeons prefer to manipulate the free end of the suture with their left hand during two-hand ties. In such cases, the right hand performs the major manipulation of the suture during forma-

tion of the loop. An advantage of this technique is that a surgeon who ties his/her own knots by the two-hand technique during wound closure can hold the needle holder in his/her right hand during knot construction. If one desires to learn to tie knots using the left hand to manipulate the free end of the suture, study the illustrations in a mirror.

Using the one-hand tie, one hand forms the suture loop while manipulating the free suture end. The other hand merely holds the other suture end taut. Most surgeons prefer to manipulate the free suture end with their left hand, allowing them to hold the needle holder in their right hand while they construct knots with their left hand.

There are several important recommendations for selecting a knot tying technique. First, position the hands on each side of and parallel to the suture loop. Second, grasp the appropriate suture ends and form the suture loop, without exchanging suture ends between the hands. While exchanging suture ends between the hands forms a triangular shaped suture loop, it is an unnecessary step that wastes valuable time. Third, pass the free suture end, rather than the fixed suture end, through the suture loop. Finally, reverse the position of the hands after each additional throw. Most of the knot tying techniques in this course comply with these recommendations. However, it is important to point out that the fixed end of the suture is being passed through the suture loops in the two-hand ties. Consequently, the surgeon must detach the needle from the fixed suture end before a two-hand tie.

A standard format for illustrating surgical knot tying techniques has been used throughout this continuing educational course. A horizontal incision is pictured in the top of each illustration. Because the wound edges are subjected to static tensions, there is retraction of the wound edges, with exposure of the underlying tissue. The surgeon is standing facing the wound from the bottom of each illustration. Because the surgeon usually passes the needle swaged to a suture toward himself/herself, the fixed end of the suture with its attached needle enters the farther side of the mid-portion of the wound and exits from the side of the wound closer to the surgeon. The suture end farthest from the surgeon is grasped between the distal phalanges of the left thumb and index finger (tip-to-tip pinch). The tips of the distal phalanges of the thumb and index finger of the right hand grasp the suture end exiting from the wound edge closer to

the surgeon. The grasped fingers apply constant tension to the suture ends. The security of this tip-to-tip pinch can be enhanced by grasping the suture ends between the tips of the long fingers, ring fingers, small fingers, and the palm of each hand.

The tying of the square, slip, and surgeon's knots using manual and instrument-tying techniques are illustrated. The technique of tying slip knots has been included in the manual because it is an excellent method to approximate temporarily the edges of wounds subjected to strong tensions. In fact, a slip knot has greater holding power than either a single-wrap or double-wrap throw.⁴⁷ Once there is a meticulous approximation of the wound edges, the slip knot can be converted to a square knot, after which a sufficient number of throws are added to the knot to ensure knot security.

Surgical Needles

Surgical needles are produced from stainless steel alloys, which have excellent resistance to corrosion.⁴⁸ All true stainless steels contain a minimum of about 12% chromium, which allows a thin, protective surface layer of chromium oxide to form when the steel is exposed to oxygen. Since their development during the early 1960s, high-nickel maraging stainless steels have found extensive use in structural materials in many applications requiring a combination of high strength and durability. The basic principle of maraging consists of strengthening FeNi martensitic matrices by the precipitation of fine intermetallic phases, such as Ni³Ti. These precipitates are so small that they are only evident on transmission electron microscopy. They strengthen the metal by preventing the planes of atoms in the stainless steel from sliding over each other. A high-nickel maraging stainless steel, such as S45500, is composed of 7.5% to 9.5% nickel, 0.8% to 1.4% titanium, and 11 % to 12.5% chromium. In contrast, S42000 stainless steel is composed of 12% to 14% chromium without nickel or titanium. Scientists have successfully utilized the concept of high-nickel maraging stainless steels (S45500) to develop stainless steel wires with superior strength and ductility for use as surgical needles. Surgical needles made of a high-nickel maraging stainless steel have a greater resistance to bending and breakage than stainless steels without nickel.

A new high-nickel stainless steel, SURGALLOY™, has been used recently to manufacture sur-

gical needles.⁴⁹ Biomechanical performance studies of SURGALLOY™ cutting edge needles made of S45500 stainless steel alloy demonstrated that needles made of SURGALLOY™ had superior performance characteristics over those made of S42000. The SURGALLOY™ needles had considerably greater resistance to bending than the needle produced from the S42000 alloy. In addition, SURGALLOY™ stainless steel had almost a twofold greater resistance to fracture than the S42000 stainless steel alloy.

Components of the Needle

Every surgical needle has three basic components: swage, body, and point.

Swage

The swage is the site of attachment of the suture. Since 1914, an eyeless needle, in which the suture was attached to a drilled hole in the needle, has been used. The swaging process provides a smooth juncture between the needle and suture; needles produced by this swaging process thereby created smaller holes in tissue than did threaded eye needles. However, this swaging process was only possible for larger diameter needles (greater than 0.36 mm) because the mechanical drill could not reliably cut uniform holes in the ends of small needles. Consequently, a forming tool was used to create a channel in one half of the diameter of smaller-diameter needles with an underlying receptacle for the attachment of the suture. However, the linear splits in the walls of these smaller diameter needles increased the drag force encountered by tissues during needle passage. With the advent of the laser (yttrium-aluminum-garnet (YAG) laser), uniform holes are reliably produced in the ends of small needles, resulting in a smooth swage that encounters lower drag forces than channel needles.⁵⁰ These low-drag forces caused by laser-drilled needles are associated with minimal mechanical trauma to tissues.

The laser-drilled needles have other unique advantages over the channel needles related to the length of the swage ends. The length of the channel in channel swage needles is four times longer than that of the laser-drilled hole. Because swages are more susceptible to bending and breakage by the needle holder jaws than the body of the needle, surgeons are warned to grasp the needle with the needle holder at a site beyond the swage. In the case

of 18-mm-long needles with laser-drilled and channel swages, the depths of the laser-drilled holes and channel swages are 1.5 mm and 6.0 mm, respectively. The laser-drilled needle can be held by the needle holder jaws 3 mm from the needle end, whereas the channel swage needle is grasped 7.5 mm from the needle end. By grasping the needle close to its end, the surgeon can more easily manipulate the passage of the needle through tissue. This benefit of laser-drilled needles is accomplished without altering the needle suture attachment strength. These distinct advantages of swages produced by lasers indicate that they should eventually replace all channel swage needles.

The needle is attached to the suture by uniformly compressing the walls of the swage against the suture, creating a strong attachment force that prevents the surgeon from detaching the suture from the needle without exerting considerable force on the swage. This suture attachment force is so great that separation of the needle from the suture is accomplished more easily by cutting the suture rather than by applying sufficient force to the suture to separate it from the swage. A special swage has been created by using lower compression forces around the circumference of the swage than conventionally used, allowing the surgeon to detach the suture from the needle using relatively low detachment forces, obviating the need to cut the suture. The swage requiring lower uniform forces to detach its suture is called a variety of names (ie, pop-off control release). It was originally developed for abdominal wound closure, bolus dressings for skin grafts, and hysterectomies in which large numbers of interrupted sutures are used.

Body

The body of the needle is the portion that is grasped by the needle holder. The security with which needle holder jaws grasp the needle is influenced by the presence of teeth in the needle holder jaws, the ratchet setting of the needle holder handle, and the shape of the cross-sectional area of the needle body. Although the shape of the cross-sectional area of the body has a significant effect on needle holding security, the presence of teeth in the needle holder jaws and the ratchet setting of the needle holder handle are much greater determinants of needle holding security than is the needle body shape.⁵¹

The shape of the cross-sectional area and the geometric configuration of the length of the needle

can categorize the geometry of the needle body. The shape of its cross-sectional area will influence the security with which the needle holder jaws grasp the needle, as well as its resistance to bending. The cross-sectional areas of the bodies of different needles have the following shapes: circular, triangular, rectangular and trapezoidal. Needles with rectangular cross-sectional areas are created either by flattening the sides of the circular wire or by flattening the top and bottom of the circular wire. When the top and bottom portions of the needle body are flattened, the long axis of its rectangular cross-sectional area will gain intimate contact with the faces of the needle holder jaw. This position of the needle body between the needle holder jaws is similar to that of the needle body with a trapezoidal shape.

In both cases, the needle holding security against twisting and rotation is greater than any other needle body (side flattening rectangular shape, triangular, and circular). This benefit of enhanced needle holding security must be weighed against an associated reduced resistance to bending, as compared to that of the other needle bodies. Because we can increase the needle holding security of all needles by advancing the ratchet setting of the needle holder, we prefer side-flattened needle bodies because they exhibit greater resistance to bending than any other needle body.

The geometry of the length of the needle will have considerable influence on the surgeon's use of a surgical needle. The curvature of the needle is described in degrees of the subtended arc. The radius of the needle is the distance from the center of the needle to the body of the needle, if the curvature of the needle was continued to make a full circle. The curvature of the needle with one radius of curvature may vary from 90° (1/4), 135° (3/8), 180° (1/2), to 225° (5/8). A compound curved needle has two distinct radii of curvature. The type curvature of its tip extends 35° before it assumes a regular uniform curvature in the remaining portion of the needle body (100°).

The surgeon uses needles with a curvature of 135° to approximate divided edges of thin planar structures that are readily accessible (ie, skin), requiring a limited arc of wrist rotation to pass the needle through the tissue. It is difficult to use the 135° needle in deep body cavities because the limited arc of wrist rotation in passing this needle is usually not sufficient to expose the needle point, so that it will remain buried in the tissue and pose a challenge for the surgeon to retrieve. The 180° needle is ideally suited

for use in deep body cavities because a limited arc of wrist rotation will pass successfully the entire needle through the tissue, allowing adequate exposure of the needle point for easy retrieval of the needle by the surgeon. The surgeon uses needles with a 90° angle of curvature in microsurgery.

The compound curved needle has been primarily used to alter the geometry of 135° needles.⁵² The tight needle curvature at the point permits rapid, accurate needle passage at a selected depth and allows controlled exiting. Its design also offers a mechanical advantage over the standard needle with one radius of curvature. Although originally designed for anterior segment ophthalmic surgery, the compound curved needle now has broader clinical applications that include vascular and microvascular surgery, and dermal and skin closure.

In addition to its curvature and radius, a surgical needle can be characterized by three other measurements: chord length, needle diameter, and needle length. Chord length is the linear distance measured from the central point of the needle swage to the point of the needle. The needle diameter is the width of the original circular wire utilized in the manufacturing process for the production of the needle. Needle length is the arc length of the needle measured at the center of the wire's cross-section.

Point

The point of the needle extends from the tip of the needle to the maximum cross section of the body. Each type of needle point is designed to penetrate specific types of tissue. In general, there are needles with cutting edges, taper points, or a combination of both. Cutting edge needles have at least two opposing edges that are designed to penetrate tough tissue. When cutting edge needles have three cutting edges, the position of the third cutting edge categorizes the needle as either a conventional cutting edge needle or a reverse cutting edge needle. Use of the conventional cutting edge needle leaves a hole that is susceptible to tissue cut-through. Because its third cutting edge is on the inside, concave, curvature of the needle, the inside cutting edge causes a linear cut that is perpendicular and close to the incision, against which the suture will exert a wound closure force that may ultimately cut through the tissue. In contrast, the third cutting edge of the reverse cutting edge needle is located on the outer convex curvature of the needle. When the re-

verse cutting edge needle cuts through skin, it leaves a wide wall of tissue, rather than an incision, against which the suture exerts its wound closure force. This wall of tissue resists suture cut-through.

Specifically designed cutting edge needles have been developed for anterior segment surgery in ophthalmology. These needles underwent a modification that converted the triangular geometry to a trapezoidal or spatulated configuration by flattening the outer convex surface. This flattening process also produces a lateral widening of the needle body. In addition to ophthalmic surgery, these spatulated needles have been used successfully to repair lacerations of the nail matrix. Referred to as "spatula needles," they are flat on their concave and convex surfaces, with long side-cutting edges. The needle's side-cutting edges separate or split through the thin lamellar plane of corneal and scleral tissue with minimal damage.

The sharpness of cutting edge needles is increased by electrohoning, narrowing the needle point configuration, narrowing the cutting edge angles, and by providing a silicone coating. When the needle is electrohoned, the surface of the needle is polished while its edges are sharpened. Narrowing the point configuration of the cutting edge needle will also enhance its sharpness.

The taper point needle tapers to a sharp tip. It spreads the tissue without cutting it. The point geometry of this needle can be measured by its taper ratio, which is the length of the tapered portion of the needle divided by its diameter. The taper ratio of these needles varies from 12:1 to 8:1. They are used in soft tissues that do not resist needle penetration, such as vessels, abdominal viscera, and fascia. They are preferred when the surgeon wants to make the smallest hole possible in tissue without cutting.

All tapercut needles combine the unique features of taper point and cutting edge needles. The cutting edges of the tapercut needle extend only a very short distance from the needle tip and blend into a round taper body. In vascular surgery, tapercut needles are used frequently for the anastomosis of calcified and fibrotic blood vessels to prosthetic grafts. Its cutting tip penetrates the calcified portion of the artery without the cutting edges of the needle body tearing the friable vessel, thereby minimizing the risk of leakage around the needle puncture. Tapercut needles have also been advocated for closure of wounds in the oral mucosa. Its short cutting edges produce a tiny hole in the oral mucosa that is considerably smaller than

that encountered with the cutting edge needles. The penetrating point needle is a tapercut needle, used by cardiothoracic and vascular surgeons, that has a diamond-shaped point with a small sharp cutting tip. Some surgeons have noted that the penetrating point needle penetrates the calcified tissue of vessels more easily than the standard tapercut needle.

Extensive clinical investigations have demonstrated that blunt tipped surgical needles dramatically reduce the risk of accidental injuries during surgery.¹ The standard taper point needle tapers to a sharp point. In contrast, the blunt taper point needle has remarkably similar geometry to that of the taper point needle, except that its point has a blunt ending at the tip of the needle. The geometry of the blunt point needle differs from those of the taper point and blunt taper point needles. Instead of tapering to either a sharp or dull tip, it has no taper at all. Biomechanical performance studies demonstrated that either the blunt taper point or the blunt point needle dramatically enhance the resistance to needle penetration of either single or double gloves.¹

The biomechanical performance of surgical needles and needle holders is determined by the following parameters: (1) needle sharpness, (2) needle resistance to bending, (3) needle ductility, and (4) needle holder clamping moment.⁵³ A sharpness tester measures the force needed to pass a needle through a membrane that simulates the density of human tissue. Manufacturers measure needle resistance to bending in the laboratory by recording the force required to bend the needle 60° or 90° to determine the needle's ultimate bending moment. The more critical measurement to the surgeon is the needle's yield moment, the force required to irreversibly deform the needle. Ductility is a measurement of the needle's resistance to breakage. The needle holder clamping moment is a measure of the force exerted by the needle holder jaws on a curved surgical needle.

Needle Holder

The needle holder is an instrument designed to hold a curved surgical needle. It consists of two first class levers (female and male members) that rotate on a common fulcrum. The portions of the levers that grasp the needle are distal to the fulcrum and are called the jaws. The remaining portion of the lever, that portion which is held by the surgeon, is called the handle. On the end of the handle portion of each shank is a

ringlet through which a fingertip can be placed. Once the jaws have gripped the needle, the surgeon can engage a locking mechanism to secure the needle in the needle holder jaws. The locking mechanism consists of individual ratchets with engaging teeth that are attached to each handle next to the ringlets. Once the ratchets are engaged, the needle holder will grasp the needle without the surgeon applying further force to the ringlets because the handles are bent to engage the ratchets, thereby producing a spring force to disengage the ratchets. The angle of each engaging tooth of the ratchet mechanism should be 39° rather than 45° to enhance the security of the engagement of the interlocking teeth.

The box lock is the junction where the female member and the male member are secured, forming the pivoting feature. The box lock is located at the site of the fulcrum of the needle holder. The chamfer is the edge of the ends of the box lock, being the end edge of the box lock at the jaw and the end edge of the box lock at the handle near the fulcrum. When the needle holder jaws are closed, there should be a space between the opposing chamfer edges so that a suture can slide easily through. In addition, the edges of the chamfer must be rounded to prevent injury to the suture.

Selecting the appropriate needle holder for a designated needle can be accomplished by relating the clamping moment of the needle holder, at the specified ratchet setting, to the yield moment for the needle placed in a measured site in the needle holder jaws. Ideally, the surgeon should use a needle holder whose clamping moment is less than that of the yield moment of the needle. When the clamping moment of the needle holder exceeds the needle yield moment, clamping the needle between the jaws of the needle holder will result in irreversible needle deformation, with a subsequent enlargement of needle chord length.

The design of the needle holder jaw is another important consideration in the selection of a needle holder. Diamond-Jaw® needle holders grasp surgical needles far more securely than conventional needle holders. They feature hard, sharp diamond-cut teeth in inserts of hardened tungsten carbide bonded to the jaw of the instrument. This highly durable insert securely grips the needle, preventing it from rotating or slipping. Tungsten carbide inserts with teeth varying from 2,500 to 7,000 teeth/in² have been incorporated into the jaws of the needle holder to enhance

the jaws' needle holding security.⁵⁴ The presence of teeth within the needle holder jaws limits twisting and rotation of the needle as compared with needle holder jaws without teeth. These teeth stabilize the needle, allowing the surgeon to control accurately the passage of the needle through the tissue.

While appreciating the potential benefits for tungsten carbide jaw inserts with teeth in achieving needle holding security, the surgeon should also realize the potential deleterious effects of the teeth on suture materials and needles. These teeth can produce distinct morphologic changes in monofilament synthetic sutures that markedly reduce the sutures' breaking strength.⁵⁵ The implications of this sutural damage on the strength of continuous monofilament synthetic suture in surgery are obvious. Finally, these teeth can alter the structural configuration of needles by producing stress concentrations, thereby reducing their resistance to either bending or breakage.⁵⁵

Smooth needle holder jaws with rounded edges do not induce structural damage to either the monofilament sutures or needles.⁵⁵ However, their smooth jaw surface provides limited resistance to either twisting or rotation of the needle between the jaws. A textured needle holder jaw metallurgically bonded with tungsten carbide particles (Snowden Pencer, division of Cardinal Health, Tucker, GA) appears to be an attractive alternative to both smooth needle holder jaws and those with teeth.⁵⁵ Although its needle holding security is significantly less than the jaws with teeth, it provides greater needle holding security than the smooth jaws. By enhancing the average surface roughness of the jaw, the embedded tungsten carbide particles of the textured jaw surface resist twisting and rotational movement of the needle. Unlike the sutural damage inflicted by the jaws with teeth, compression of the synthetic monofilament suture by either the rounded smooth jaws or textured jaws with tungsten carbide particles does not weaken the monofilament suture.

Recent studies demonstrate that the sharp outer edges of some smooth needle jaws cut the smooth surface of the monofilament suture during instrument ties, weakening the strength of the suture.⁵⁵ When the smooth needle holder jaws clamp 6-0 monofilament nylon suture with their first opposing teeth, there is a significant reduction in suture breaking strength. This sutural damage can be prevented by mechanically grinding the outer edges of the smooth tungsten

carbide inserts, yielding a rounded edge. Clamping the suture with the smooth jaws of the needle holder with rounded edges is atraumatic, with no demonstrable damage to the suture's breaking strength. The sharp edges of the box lock of the fulcrum of the needle holder are another cause of sutural damage during instrument ties. Consequently, the box lock of new needle holders has been manufactured with beveled edges that do not entrap or cut the suture.

Packaging System for Surgical Needles and Sutures

Packages for surgical needles swaged to sutures have been designed to achieve several specific objectives.⁵⁶ First, the package and its contents must be susceptible to sterilization. Second, the package must afford convenient and sterile transfer of the surgical needles swaged to sutures to the sterile field. The needle must be protected to prevent dulling of its cutting edges and point. Finally, the suture must be kept as straight as possible until knot construction.

Each suture swaged to its needle is contained within at least two layers of packaging. These two layers allow sterile transfer to the sterile field. The "breather" or outer pouch is made of a laminate of Tyvek™ on one side and heat sealed to plastic film on the other. The exterior surfaces of this overwrap are not considered sterile. The inside surfaces of the overwrap and primary packet within it are sterile so long as the overwrap remains intact and undamaged. The Tyvek™ backing is permeable to ethylene oxide resulting in reliable gas sterilization of the inside of the overwrap as well as the inner packet containing the suture swaged to the needle. The outer wrap has two flaps that are peeled apart, allowing transfer of the inner packet to the sterile field. The outer wraps for the packages containing either absorbable or non-absorbable sutures swaged to needles have identical dimensions and construction.

The overwrap has two flaps that are peeled apart, allowing transfer of the inner packet to the sterile field. Once the overwrap is peeled apart, the inner packet is transferred to the sterile field without contaminating it. The transparent plastic film is shorter than the backing, allowing it to be easily separated from the backing. A row of indentations in the plastic film enhances the security of grasp.

The design of the inner packet for absorbable sutures is different from that for nonabsorbable su-

tures. Because absorbable sutures must be protected from moisture, the sterile inner packets are hermetically sealed aluminum foil cavities that are designed to be functional tear foil packets. The upper edge of the sterile inner packet has a tear notch that provides consistent easy opening of the foil packet. A TEAR RIGHT indicator is printed on the front of the package to indicate the direction of tearing the foil packet. Tearing the package in the direction of the indicator allows easy access to the needle “parked” in foam that can be armed by right-handed surgeons. Note that each packet has easy to read graphics with the designated expiration date listed for all absorbable suture products.

The inner packet for nonabsorbable sutures has several unique features. It has a mid-peel opening in its packet with an access flap that is lifted from the inner packet and turned 180° to expose the body of the needle whose point and cutting edges are “parked” in foam. By rotating the access flap 180°, the needle is armed by the needle holder from either side of the packet by right- or left-handed surgeons. The needle is positioned in a manner that prevents kinking of the monofilament suture near the swage of the needle.

For either absorbable or nonabsorbable sutures, unique systems have been designed to stabilize the braided and monofilament suture in their packet. For the braided sutures, a retainer of rigid plastic film having a spiral labyrinth is specially designed for delivery of a kink-free suture. The suture exits from the labyrinth in a manner that maintains the suture’s straight uniform configuration. The suture is swaged to a needle that is “parked” in foam that protects the delicate needle point and its cutting edges.

The physical and chemical properties of monofilament sutures are distinct from those of braided sutures, causing manufacturers to design a special packing system for monofilament sutures. The plastic memory of the monofilament suture is so great that the shape of the suture conforms to the shape of the packet. Consequently, the monofilament suture is not packaged in a circular configuration, which would cause the suture to assume a coiled configuration. A coiled monofilament suture is an invitation to the knotting of the suture. The monofilament suture is wrapped around four fixation pins in the figure-of-eight shaped loops. The monofilament suture can be straightened to a more linear configuration by applying forces to the suture ends.

References

1. Edlich RF, Wind TC, Hill LG, Thacker JG, McGregor W. Reducing accidental injuries during surgery. *J Long Term Eff Med Implants*. 2003;13(1):1-10.
2. Edlich RF, Panek PH, Rodeheaver GT, Turnbull VG, Kurtz LD, Edgerton MT. Physical and chemical configuration of sutures in the development of surgical infection. *Ann Surg*. 1973 Jun;177(6):679-688.
3. Postlethwait RW. Long-term comparative study of non-absorbable sutures. *Ann Surg*. 1970;171:892-898.
4. Rodeheaver GT, Nesbit WS, Edlich RF. Novafil, a dynamic suture for wound closure. *Ann Surg*. 1986;204:193-199.
5. Trimbos JB, Smeets M, Verdel M, Hermans J. Cosmetic result of lower midline laparotomy wounds: polybutester and nylon skin suture in a randomized clinical trial. *Obstet Gynecol*. 1993;82(3):390-393.
6. Pinheiro AL, de Castro JF, Thiers FA, Cavalcanti ET, Rego TI, de Quevedo AS, Lins AJ, Aca CR. Using Novafil: would it make suturing easier? *Braz Dent J*. 1997;8(1):21-25.
7. Dang MC, Thacker JG, Hwang JC, Rodeheaver GT, Melton SM, Edlich RF. Some biomechanical considerations of polytetrafluoroethylene sutures. *Arch Surg*. 1990;125(5):647-650.
8. Rodeheaver GT, Shimer AL, Boyd LM, Drake DB, Edlich RF. An innovative absorbable coating for the polybutester suture. *J Long Term Eff Med Implants*. 2001;11(1 & 2):41-54.
9. Lewis RP, Schweitzer J, Odum BC, Lara WC, Edlich RF, Gampfer TJ. Sheets, 3-D strands, trimensional (3-D) shapes, and sutures of either reinforced or nonreinforced expanded polytetrafluoroethylene for facial soft-tissue suspension, augmentation and reconstruction. *J Long Term Eff Med Implants*. 1998;8:19-42.
10. Towler MA, Tribble CG, Pavlovich IJ, Milam JT, Morgan RF, Edlich RF. Biomechanical performance of new vascular sutures and needles for use in polytetrafluoroethylene grafts. *J Appl Biomater*. 1993;4(1):87-95.
11. Miller CM, Sangiolo P, Jacobson JH II. Reduced anastomotic bleeding using new sutures with a needle-suture diameter ratio of one. *Surgery*. 1987;101(2):156-160.
12. Tera H, Åberg C. Strength of knots in surgery in relation to type of knot, type of suture material and dimension of suture thread. *Acta Chir Scand*. 1977;143(2):75-83.
13. Salthouse TN, Williams JA, Willigan DA. Relationship of cellular enzyme activity to catgut and collagen suture absorption. *Surg Gynecol Obstet*. 1981;129:691-696.

14. Rodeheaver GT, Thacker JG, Edlich RF. Mechanical performance of polyglycolic acid and polyglactin 910 synthetic absorbable sutures. *Surg Gynecol Obstet.* 1981;153:835-841.
15. Faulkner BC, Gear AG, Hellewell TB, Mazzarese PM, Watkins FH, Edlich RF. Biomechanical performance of a braided absorbable suture. *Surg Gynecol Obstet.* 1981;153:497-507.
16. Drake DB, Rodeheaver PE, Edlich RF, Rodeheaver GT. Experimental studies in swine for measurement of suture extrusion. *J Long Term Eff Med Implants.* 2004;14(3):251-259.
17. Storch M, Perry LC, Davidson JM, Ward JJ. A 28-day study of the effect of coated VICRYL™ plus antibacterial suture (coated polyglactin 910 suture with triclosan) on wound healing in guinea pig linear incisional skin wounds. *Surg Infect.* 2002;3 Suppl 1S89-98.
18. Rothenburger S, Spangler D, Bhende S, Burkley D. In vitro antimicrobial evaluation of coated VICRYL™ plus antibacterial suture (coated polyglactin 910 with triclosan) using zone of inhibition assays. *Surg Infect.* 2002;3 Suppl 1:79-87.
19. Ray JA, Doddi N, Regula D, Williams JA, Melveger A. Polydioxanone (PDS), a novel monofilament synthetic absorbable suture. *Surg Gynecol Obstet.* 1981;153:497-507.
20. Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surg Gynecol Obstet.* 1985;161:213-222.
21. Rodeheaver GT, Beltran KA, Green CW, Faulkner BC, Stiles BM, Stanimir GW, Traeland H, Fried GM, Brown HC, Edlich RF. Biomechanical and clinical performance of a new synthetic monofilament suture. *J Long Term Eff Med Implants.* 1996;6:181-196.
22. Pinos-Fernandez A, Drake DB, Rodeheaver PA, Moody DL, Edlich RF, Rodeheaver GT. CAPROSYN™, another major advance in synthetic monofilament absorbable suture. *J Long Term Eff Med Implants.* 2005;14(5):359-368.
23. Edlich RF, Tsung MS, Rogers W, Rogers P, Wangenstein OH. Studies in the management of the contaminated wound: I. Techniques of closure of such wounds together with a note on a reproducible model. *J Surg Res.* 1968;8:585-592.
24. Edlich RF, Panek PH, Rodeheaver GT, Turnbull VG, Kurtz LD, Edgerton MT. Physical and chemical configuration of sutures in the development of surgical infection. *Ann Surg.* 1973;177:679-688.
25. Sharp WV, Belden TA, King PH, Teague PC. Suture resistance to infection. *Surgery.* 1982;91:61-63.
26. deHoll D, Rodeheaver G, Edgerton MT, Edlich RF. Potentiation of infection of suture closure of dead space. *Am J Surg.* 1974;127:716-720.
27. Foster GE, Hardy EG, Hardcastle JD. Subcuticular suturing after appendectomy. *Lancet.* 1977; 1: 1128-1129.
28. Hopkinson GB, Bullen BR. Removable subcuticular skin suture in acute appendicitis: a prospective comparative clinical trial. *BMJ (London).* 1982;284:869.
29. Polglase A, Nayman J. A comparison of the incidence of wound infection following the use of percutaneous and subcuticular suture: an experimental study. *Aust N Z J Surg.* 1977;47:423-425.
30. Pham S, Rodeheaver GT, Dang MC, Foresman PA, Hwang JC, Edlich RF. Ease of continuous dermal suture removal. *J Emerg Med.* 1990;8:539-543.
31. Winn HR, Jane JA, Rodeheaver G, Edgerton MT, Edlich RF. Influence of subcuticular sutures on scar formation. *Am J Surg.* 1977;133:257-259.
32. Nordström REA, Nordström RM. Absorbable versus nonabsorbable sutures to prevent postoperative stretching of wound areas. *Plast Reconstr Surg.* 1986;78:186-190.
33. McGuire MF. Studies of the excisional wound: I. Biomechanical effects of undermining and wound orientation on closing tension and work. *Plast Reconstr Surg.* 1980;66:419-427.
34. Thacker JG, Rodeheaver GT, Moore JW, Kauzlarich JJ, Kurtz L, Edgerton MT, Edlich RF. Mechanical performance of surgical sutures. *Am J Surg.* 1975;130:374-380.
35. Edlich RF, Rodeheaver GT, Thacker JG. The evaluation of wounds in the emergency department. In: *Emergency Medicine: A Comprehensive Study Guide, Second Edition*, (eds.) Tintinalli JE, Krome RL, Ruiz E, McGraw-Hill Book Co. 1987, p. 929-932.
36. Taylor FW. Surgical knots. *Ann Surg.* 1938;107:458-468.
37. Tera H, Åberg C. Tensile strength of twelve types of knot employed in surgery, using different suture materials. *Acta Chir Scand.* 1976;142:1-7.
38. Rodeheaver GT, Borzelleca DC, Thacker JG, Edlich RF. Unique performance characteristics of Nova-fil®. *Surg Gynecol Obstet.* 1987;142:230-360.
39. Zimmer CA, Thacker JG, Powell DM, Bellian KT, Becker DG, Rodeheaver GT, Edlich RF. Influence of knot configuration and tying technique on the mechanical performance of sutures. *J Emerg Med.* 1991;9:107-113.
40. Howes EL, Harvey SC. The strength of the healing wound in relation to the holding strength of the catgut suture. *N Engl J Med.* 1929; 200:1285-1290.
41. Holmlund DE. Knot properties of surgical suture materials. A model study. *Acta Chir Scand.* 1974;140:355-362.
42. Tera H, Åberg C. Strength of knots in surgery in relation to type of knot, type of suture material

- and dimension of suture thread. *Acta Chir Scand.* 1977;143(2):75-83.
43. Åberg C. Change in strength of aponeurotic tissue enclosed in the suture during the initial healing period. An experimental investigation in rabbits. *Acta Chir Scand.* 1976;142:429-432.
 44. Nichols WK, Stanton M, Silver D, Keitzer WF. Anastomotic aneurysms following lower extremity revascularization. *Surgery.* 1980;88:366-374.
 45. Stamp CV, McGregor W, Rodeheaver GT, Thacker JG, Towler MA, Edlich RF. Surgical needle holder damage to sutures. *Am Surg.* 1988;54:300-306.
 46. Abidin MR, Towler MA, Thacker JG, Nochimson GD, McGregor W, Edlich RF. New atraumatic rounded-edge surgical needle holder jaws. *Am J Surg.* 1989;157:241-242.
 47. Dobrin PB. Surgical manipulation and the tensile strength of polypropylene sutures. *Arch Surg.* 1989;124:665-668.
 48. Edlich RF, Thacker JG, McGregor W, Rodeheaver GT. Past, present and future for surgical needles and needle holders. *Am J Surg.* 1993;166:522-532.
 49. Watkins FH, London SD, Neal JG, Thacker JG, Edlich RF. Biomechanical performance of cutting edge surgical needles. *J Emerg Med.* 1997;15:679-685.
 50. Ahn LC, Towler MA, McGregor W, Thacker JG, Morgan RF, Edlich RF. Biomechanical performance of laser-drilled and channel taper point needles. *J Emerg Med.* 1992;10:601-606.
 51. Thacker JG, Borzelleca DC, Hunter JC, McGregor W, Rodeheaver GT, Edlich RF. Biomechanical analysis of needle holding security. *J Biomed Mat Res.* 1986;20:903-917.
 52. Abidin MR, Becker DG, Paley RD, Doctor A, Westwater JJ, McGregor W, Edlich RF. A new compound curved needle for intradermal suture closure. *J Emerg Med.* 1989;7:441-444.
 53. Bond RF, McGregor W, Cutler PV, Becker DG, Thacker JG, Edlich RF. Influence of needle holder jaw configuration on the biomechanics of curved surgical needle bending. *J Appl Biomat Res.* 1990;1:39-47.
 54. Thacker JG, Borzelleca DC, Hunter JC, McGregor W, Rodeheaver GT, Edlich RF. Biomechanical analysis of needle holding security. *J Biomat Res.* 1986;20:903-917.
 55. Abidin MR, Dunlapp JA, Towler MA, Becker DG, Thacker JG, McGregor W, Edlich RF. Metallurgically bonded needle holder jaws. A technique to enhance needle holding security without sutural damage. *Am Surg.* 1990;56:643-647.
 56. Noriega LK, Rodeheaver GT, Thacker JG, Edlich RF. Modern concepts of packaging surgical needles and suture. *Med Prog Tech.* 1994; 20:271-279.

Scientific Basis for the Selection of Skin Closure Techniques

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This scientific article was designed to teach the individual reader the scientific basis for suture and needle selection as well as to illustrate the appropriate surgical techniques involved in wound repair of skin incisions. Because the US Food and Drug Administration permits 1.5% of the sterile surgical gloves to have holes, the operating room personnel should wear sterile surgical double-glove hole indication systems that detect holes in the outer glove. From the surgeon's point of view, the rate of gain of strength of the skin wound is a key determinant of many decisions including when the suture can be removed, the level of patient activity, and the selection of the incision. Important considerations in wound closure are type of suture and mechanical performance, *in vivo* and *in vitro*. Measurements of the *in vivo* degradation of sutures separate them into two general classes, *absorbable* and *nonabsorbable*. Sutures that undergo rapid degradation in tissues, losing their tensile strength within 60 days, are considered absorbable. Those that maintain their tensile strength for longer than 60 days are considered nonabsorbable. For skin closure with nonabsorbable suture, we favor the use of the polybutester suture that is coated with an absorbable polymer, VASCUFIL™. When absorbable sutures are used for a dermal skin closure, the synthetic monofilament MAXON™ is recommended. Absorption of the suture is complete between 90 and 110 days. In either case, we would recommend that the suture be attached by a swage attachment to a SURGALLOY™ reverse cutting stainless steel suture. Continuous percutaneous suture closure has definite, distinct advantages over interrupted suture closure. Although continuous dermal wound closure is technically more challenging for the surgeon than interrupted dermal suture closure, it has become an important wound closure technique. A monofilament absorbable synthetic MAXON™ attached to a reverse cutting edge SURGALLOY™ stainless steel needle is ideally suited for continuous dermal skin suture closure.

KEY WORDS: epidermis, dermis, percutaneous suture, dermal suture, double-glove hole indication system

Introduction

If this scientific report heightens the surgeon's, resident's, and student's interest in the biology of wound closure and infection, the long years occupied in our search for improved methods of wound management would more than fulfill our expectations. Through the ages, selection of surgical sutures, needles and gloves has been an important consideration for surgeons. Despite these important historical considerations, some surgeons perceive surgical suture, needle and glove selection more as an art than as a science. For those artisans, the use of methods and materials for suturing and glove selection is usually a matter of habit, guesswork, or tradition. This approach to suturing has contributed to a growing concern that the suture selections as well as knot tying techniques employed by many surgeons are not optimal and that they incorrectly select sutures and use faulty techniques in tying knots, which is the weakest link in a tied surgical suture. When the recommended configuration of a knot ascertained by mechanical performance tests was compared to those used by board-certified general surgeons, only 25% of surgeons used the appropriate knot construction.¹ Of the twenty-five gynecologists, mostly department heads, who were polled about their knot tying technique, most were convinced that they made square knots, even though their knot-tying techniques resulted in slipped knots that became untied.² When a knotted suture fails to perform its functions, the consequences may be disastrous. Massive bleeding may occur when the suture loop surrounding a vessel becomes untied or breaks. Wound dehiscence or incisional hernia may follow knot disruption.

As with any master surgeon, he/she must understand the tools of his/her profession. This linkage between a surgeon and surgical equipment is a closed kinematic chain in which the surgeon's power is converted into finely coordinated movements that result in wound closure with the least possible scar and without infection.

Surgeons have transformed surgical suture and needle selection from a ritual practice to a surgical discipline. Early in our careers, surgical selection of sutures and needles was largely based on testimonials and anecdotal experiences of senior surgeons. Today, modern surgeons select sutures and needles on the basis of well-controlled, randomized clinical and experimental trials. Having a keen appreciation

of surgical education, we have modeled the format of this report to be an individualized learning environment. This scientific article was designed to teach each participant the scientific basis for suture and needle selection as well as to illustrate the appropriate surgical techniques involved in wound repair of skin incisions.

Sutural Skin Closure

All operating room personnel should wear powder-free surgical gloves because the cornstarch glove mold release agent causes tissue injury and serves as a vector for latex allergy.³ Participants sensitized to latex should wear powder-free, latex-free surgical gloves.⁴ Because the US Food and Drug Administration permits 1.5% of the sterile surgical gloves to have holes, the operating room personnel should wear sterile surgical double-gloves. Because most surgical glove hole punctures go unnoticed for some time after perforation even with double-gloves, many operating room personnel are now using a double-glove hole puncture indication system (Molnlyke Health Care, Inc.).⁵ When the outer glove is punctured, the colored inner glove is exposed to blood and other fluids in the operative procedure. After exposure to fluids, this double-glove puncture indication system develops the appearance of a darker color around the outer glove puncture site, a warning to operating room personnel to the presence of glove puncture of the outer glove. After noting this color change, the operating room personnel must remove all surgical gloves, wash hands and don a new double-glove puncture indication system.⁶ Following needlestick injury of operating room personnel, postexposure prophylaxis is mandatory.

Biology of Skin Wound Repair

From the surgeon's point of view, the rate of gain of strength of the skin wound is a key determinant of many decisions including when the suture can be removed, the level of patient activity, and the selection of the incision. The answers to these questions are found in the results of bioengineering studies of the strength of skin wounds. Even though collagen fibers are evident on the third day after injury, the skin wound has negligible tensile strength.⁷ During the first eight days after closure, the wound is held together by blood vessels crossing the wound, epithelialization, and a fibrinous coagulum. If the percutaneous

sutures are removed at this time, the wound may be disrupted easily unless supported by dermal sutures and/or skin closure tapes. Over the next 13 days (8 to 21 days after injury), there is a rapid gain in strength of skin wounds. They continue to gain strength at a relatively rapid and constant rate for four months and at a slower rate for one year. The strength of repaired skin incisions never reaches that of uninjured skin. Adamsons and Kahan demonstrated that rabbit skin wounds closed with a continuous 4-0 silk suture regained only 40% of the strength of unwounded tissue 120 days after wounding.⁸ In the dog, Van Winkle and associates noted that skin wounds approximated by different percutaneous sutures developed 70% of their normal strength by 120 days.⁹ Consequently, the skin wound remains a relatively brittle structure that is capable of absorbing much less energy than normal skin.

The diminished tensile strength of wounded skin as compared with normal skin can be correlated with histological appearance.¹⁰ The morphologic features of scarred collagen differ distinctly from collagen in unwounded tissue, particularly collagen bundle size. Wound collagen bundles are narrower than normal collagen. Polarized light studies indicate that there is also a more generalized disorganization of the wound collagen.

Normal collagen is birefringent, whereas wound collagen is clearly a non-birefringent material, which indicates a relatively disorganized structure at the molecular or small fibril level. Physical irregularities in fiber shape and "weave" are more readily appreciated by scanning electron microscopic examination. Scanning electron micrographs of a normal collagen fiber show that it is made up of bundles of cross-banded fibrils, characteristically organized into an interlacing network. In the healing wound, the fibers lie in a haphazard pattern. As time passes, the randomly dispersed collagen bundles coalesce to form irregular masses of collagen. Close examination of the wound shows no evidence of the collagen fibril structure. Unfortunately, scar collagen appears to be fixed irretrievably in this haphazard arrangement.

Through the years, imaginative biologists have suggested methods to accelerate healing. To date, this avenue of research has resulted in important findings on the repair of dehiscence and resutured wounds. Incised wounds allowed to heal for short periods, then dehiscence and immediately resutured, developed strength at a significantly faster rate than

the primary wound.¹¹ Experiments in animals demonstrated that strength gained in secondary wound healing correlated with the rate of collagen synthesis at the time of dehiscence rather than the collagen content of the wounds.¹² Interestingly, excision of the wound edges and reapproximation of the debrided edges eliminated this acceleration of healing.¹³ Such debridement of the wound edges of a dehiscence wound is therefore clearly an error in surgical judgment. The benefits of secondary wound healing can be realized in patients requiring surgical intervention soon after the first procedure. Patients with wounds exhibiting gross malapposition of skin edges should be returned immediately to the operating theater to reapproximate these edges. The development of complications, such as ischemia of the wound edges or hematoma, also warrants re-exploration of the wound. When performed between the first and fourth week after injury, the secondary wound exhibits a greater breaking strength than the first. This accelerated healing is associated with enhanced resistance of the wound to infection.¹⁴

Sutures

Important considerations in wound closure are type of suture and mechanical performance, *in vivo* and *in vitro*. Measurements of the *in vivo* degradation of sutures separate them into two general classes, *absorbable* and *nonabsorbable*. Sutures that undergo rapid degradation in tissues, losing their tensile strength within 60 days, are considered absorbable. Those that maintain their tensile strength for longer than 60 days are considered nonabsorbable. This terminology is somewhat misleading, because even some nonabsorbable sutures (ie, silk and nylon) lose a degree of tensile strength during this 60-day interval. Postlethwait¹⁵ measured the tensile strength of implanted nonabsorbable sutures during a period of 2 years. Silk lost approximately 50% of its tensile strength in 1 year and had no strength at the end of the 2 years. Nylon lost approximately 25% of its original strength throughout the 2-year observation period.

Nonabsorbable Sutures

The nonabsorbable sutures of Syneture™ Sutures (division of Covidien Inc., Norwalk, CT) can be classified according to their origin. Nonabsorbable sutures made from natural fibers are *silk* sutures. *Me-*

tallic sutures are derived from stainless steel. Modern chemistry has developed a variety of synthetic fibers including polyamides (nylon), polyesters (Dacron™), polyolefins (polyethylene, polypropylene), polytetrafluoroethylene, and polybutester.

Polypropylene is a linear hydrocarbon polymer that consists of a strand of polypropylene, a synthetic-linear polyolefin. All polypropylenes begin with a base resin and then go through the following steps: extrusion, drawing, relaxation, and annealing. Each step in the process will influence the ultimate biomechanical performance of the suture. Biomechanical studies influence the surface characteristics without altering strength. Changes in the surface characteristics can facilitate knot construction of the suture. The polypropylene suture SURGIPRO™ has a low coefficient of friction that facilitates knot rundown and suture passage through the tissue. A new polypropylene suture, SURGIPRO™ II, has increased resistance to fraying during knot rundown, especially with smaller diameter sutures. Polypropylene sutures are extremely inert in tissue and have been found to retain tensile strength in tissues for as long as 2 years. Polypropylene sutures are widely used in plastic, cardiovascular, general, and orthopedic surgery. In tissue, they exhibit a lower drag coefficient than nylon sutures, making them ideal for use in continuous suture closure.

Nylon is polyamide polymer that is extruded into a monofilament suture (MONOSOF™, DERMALON™). Although it has high tensile strength and low tissue reactivity, it degrades by hydrolysis *in vivo* at a rate of about 12.5% per year. The pliability characteristics of nylon sutures permit good handling. Because they are more pliable and easier to handle than polypropylene sutures, they are favored for the construction of interrupted percutaneous suture closures. However, polypropylene sutures encounter lower drag forces in tissue, which accounts for their frequent use in continuous dermal and percutaneous suture closure. Nylon sutures are also available in a braided construction (SURGILON™), which are relatively inert in tissue and possess the same handling and knot construction characteristics as natural fiber, silk sutures (SOFILK™).

Polyester sutures (SURGIDAC™, TI•CRON™) are composed of fibers of polyester, or polyethylene terephthalate, a synthetic linear polyester derived from the reaction of a glycol and a dibasic acid. Polyester sutures were the first synthetic braided sutures shown to last indefinitely in tissues. Their acceptance

in surgery was initially limited because the suture had a high coefficient of friction, which interfered with passage through tissue and with knot construction. However, when the sutures were coated with a lubricant, they gained wide acceptance in surgery. This coating markedly reduced the sutures' coefficient of friction, thereby facilitating knot construction and passage through tissue. The surface lubricants vary from polybutylene adipate (SURGIDAC™) to silicone (TI•CRON™).

The polybutester suture (NOVAFIL™) is a block copolymer that contains butylene terephthalate and polytetramethylene ether glycol. Polybutester sutures have unique performance characteristics that may be advantageous for wound closure.¹⁶ This monofilament synthetic nonabsorbable suture exhibits distinct differences in elongation compared with other sutures. With the polybutester suture, low forces yield significantly greater elongation than that found with the other sutures. In addition, its elasticity is superior to other sutures, allowing the suture to return to its original length once the load is removed. The clinical performance of polybutester sutures has been enhanced by coating its surface with a unique absorbable polymer (VASCUFIL™).¹⁷ This coating is a POLYTRIBOLATE™ polymer composed of three compounds: glycolide, ε-caprolactone, and poloxamer 188. Coating the polybutester suture markedly reduces its drag forces in musculoaponeurotic, colonic, and vascular tissue.

The nonabsorbable sutures also may be characterized by their physical configurations. Sutures constructed from one filament (nylon, polypropylene, polybutester, polytetrafluoroethylene, and stainless steel) are called *monofilament* sutures. Sutures containing multiple fibers (nylon, polyester, stainless steel, and silk) are called *multifilament* sutures.

Only nylon and stainless steel sutures are available as both a monofilament and multifilament suture. Monofilament stainless steel (SURGISTEEL™) is manufactured as varying-diameter single strands of stainless steel. Multifilament stainless steel sutures (FLEXON™) are formed by winding one filament around another, forming a twisted suture. Long, continuous strands of stainless steel are twisted together to form sutures of various gauges.

The other multifilament sutures are formed by intertwining three or more filaments. For instance, several very fine silk fibers are twisted together to form yarns, which are then braided. The number of

silk fibers used regulates the suture gauge; a large gauge suture can be made with braids of synthetic filaments by increasing either the number or the size of the filaments.

Absorbable Sutures

The absorbable sutures of Syneture™ Sutures (division of Covidien Inc., Norwalk, CT) are made from either collagen or synthetic polymers. The collagen sutures are derived from the submucosal layer of ovine small intestine or the serosal layer of bovine small intestine (gut). This collagenous tissue is treated with an aldehyde solution, which cross-links and strengthens the suture and makes it more resistant to enzymatic degradation. Suture materials treated in this way are called *plain gut*. If the suture is also treated with chromium trioxide, it becomes *chromic gut*, which is more highly cross-linked and more resistant to absorption than plain gut. When this treatment of collagen sutures is limited, the result is a special form of chromic gut, MILD CHROMIC GUT, which is more susceptible to tissue absorption. Plain gut and chromic gut sutures comprise several plies that have been twisted slightly, machine ground, and polished, yielding a relatively smooth surface that is monofilament-like in appearance. Salthouse et al. demonstrated that the mechanism by which gut reabsorbs is the result of sequential attacks by lysosomal enzymes.¹⁸ In most locations, this degradation is started by acid phosphatase, with leucine aminopeptidase playing a more important role later in the absorption period. Collagenase is also thought to contribute to the enzymatic degradation of these collagen sutures.

The type of gut being used determines the rate of absorption of surgical gut. Plain gut is rapidly absorbed. Its tensile strength is maintained for only 7-10 days post implantation, and absorption is complete within 70 days. A limited exposure to chromium trioxide accelerates tensile strength loss and absorption of MILD CHROMIC GUT. This fast-absorbing surgical gut is used primarily for ophthalmic and cuticular applications in which sutures are required for only 5-7 days. The tensile strength of MILD CHROMIC GUT may be retained 10-14 days.

Natural fiber absorbable sutures have several distinct disadvantages. First, they have a tendency to fray during knot construction. Second, there is considerably more variability in their retention of tensile strength than is found with the synthetic absorbable

sutures. A search for a synthetic substitute for collagen sutures began in the 1960s. Soon procedures were perfected for the synthesis of high molecular weight polyglycolic acid, which led to the development of the polyglycolic acid sutures (DEXON™ II).¹⁹ These sutures are produced from the homopolymer, polyglycolic acid. Because of the inherent rigidity of this homopolymer, monofilament sutures produced from polyglycolic acid sutures are too stiff for surgical use except in the finest size. Consequently, this high molecular weight homopolymer is extruded into thin filaments, braided, and coated with POLYCAPROLATE™.¹⁹ The polyglycolic acid sutures degrade in an aqueous environment through hydrolysis of the ester linkage.

Copolymers of glycolide and lactide were then synthesized to produce a new braided absorbable suture (POLYSORB™). The glycolide and lactide behaved differently when exposed to tissue hydrolysis. Glycolide provides for high initial tensile strength but hydrolyzes rapidly. Lactide has a slow and controlled rate of hydrolysis, or tensile strength loss, and provides for prolonged tensile strength in tissue. LACTOMER™ is a polymer consisting of glycolide and lactide in a 9:1 ratio.

The handling characteristics of POLYSORB™ sutures were found to be superior to those of the Polyglactin 910™ suture.²⁰ Using comparable knot construction and suture sizes, the knot breaking strength for POLYSORB™ sutures was significantly greater than that encountered by Polyglactin 910™ sutures. In addition, the mean maximum knot rundown force encountered with the POLYSORB™ sutures was significantly lower than that noted with the Polyglactin 910™ sutures, facilitating knot construction.

The surfaces of these synthetic sutures have been coated to decrease their coefficient of friction.²⁰ The coating on the polyglycolic acid suture was an absorbable surface lubricant, poloxamer 188, that has now been changed. POLYSORB™ sutures are coated with an absorbable mixture of caprolactone/glycolide copolymer and calcium stearoyl lactylate. At 14 days postimplantation, approximately 65% of the tensile strength of these braided sutures remains. Approximately 40% of their tensile strength is retained at 21 days. Absorption is minimal until day 40, and essentially complete between days 56 and 70.

A monofilament absorbable suture (MAXON™) has been developed using trimethylene carbonate.²¹ Glycolide trimethylene carbonate is a linear copo-

lymer made by reacting trimethylene carbonate and glycolide with diethylene glycol as an initiator and stannous chloride dehydrate as the catalyst. The latest innovation in the development of monofilament synthetic absorbable sutures has been the production of Glycomer 631, a terpolymer composed of glycolide, trimethylene carbonate, and diaxanone (BIOSYN™), which has several distinct advantages over braided synthetic absorbable sutures.²² First, it is significantly stronger than the braided synthetic absorbable suture over 4 weeks of implantation. Absorption is complete between 90 and 110 days. In addition, it potentiates less bacterial infection than does the braided suture. The handling characteristics of the monofilament suture are superior to those of the braided suture because it encounters lower drag forces in the tissue.

The strength of the MAXON™ suture is maintained *in vivo* much longer than that of the braided synthetic absorbable suture. The MAXON™ retained approximately 70% of its breaking strength after implantation for 28 days and still retained 13% of its original strength at 56 days. In contrast, braided absorbable sutures retained 1-5% of their strength at 28 days.²² Absorption of the MAXON™ suture is minimal until about day 90 postimplantation and is essentially complete within 6 months. The direct correlation of molecular weight and breaking strength of the synthetic absorbable sutures with both *in vivo* and *in vitro* incubation implies a similar mechanism of degradation. Because *in vitro* incubation provides only a buffered aqueous environment, the chemical degradation of these sutures appears to be by non-enzymatic hydrolysis of the ester bonds. Hydrolysis would be expected to proceed until small, soluble products are formed, then dissolved and removed from the implant site. In contrast, the gut or collagen suture, being a proteinaceous substance, is degraded primarily by the action of proteolytic enzymes.

A distinction must be made between the rate of absorption and the rate of tensile strength loss of the suture material. The terms *rate of absorption* and *rate of tensile strength loss* are not interchangeable. Although the rate of absorption is of some importance with regard to late suture complications, such as sinus tracts and granulomas, the rate of tensile strength loss is of much greater importance to the surgeon, considering the primary function of the suture: maintaining tissue approximation during healing.

When considering an absorbable suture's tensile strength *in vivo*, we recommend that the manufacturer

provide specific measurements of its holding capacity, rather than the percentage retained of its initial tensile strength. The United States Pharmacopoeia (USP) has set tensile strength standards for synthetic absorbable suture material. If the manufacturers were to use these standards to describe maintenance of tensile strength, the surgeon would have a valid clinical perspective with which to judge suture performance. Some manufacturers persist in reporting maintenance of the tensile strength of their suture in tissue by referring only to the percentage retained of its initial tensile strength, making comparisons among sutures difficult. Using USP standards in reporting is particularly important when there are marked differences in the initial tensile strengths of synthetic sutures. For example, the initial tensile strength of BIOSYN™ is 43% greater than that of polydioxanone. At 2 weeks, the BIOSYN™ suture is approximately 30% stronger.

Surgical Needles

The surgical needles of Syneture™ Sutures (division of Covidien Inc., Norwalk, CT) are produced from stainless steel alloys, which have excellent resistance to corrosion.²³ All true stainless steels contain a minimum of about 12% chromium, which allows a thin, protective surface layer of chromium oxide to form when the steel is exposed to oxygen. Since their development during the early 1960s, high-nickel maraging stainless steels have found extensive use in structural materials in many applications requiring a combination of high strength and durability. The basic principle of maraging consists of strengthening FeNi martensitic matrices by the precipitation of fine intermetallic phases, such as Ni₃Ti. These precipitates are so small that they are only evident on transmission electron microscopy. They strengthen the metal by preventing the planes of atoms in the stainless steels from sliding over each other. A high-nickel maraging stainless steel, such as S45500, comprises 7.5-9.5% nickel, 0.8-1.4% titanium, and 11-12.5% chromium. In contrast, S42000 stainless steel comprises 12-14% chromium without nickel or titanium. Scientists have successfully employed the concept of high-nickel maraging stainless steels (S45500) to develop stainless steel wires with superior strength and ductility for use as surgical needles. Surgical needles made of high-nickel maraging stainless steel have a greater resistance to bending and breaking than stainless steels without nickel.

A new high-nickel stainless steel, SURGALLOY™, has been used recently to manufacture surgical needles.²⁴ Biomechanical performance studies of cutting edge needles made of S45500 stainless steel alloy and SURGALLOY™ stainless steel demonstrated that needles made of SURGALLOY™ had superior performance characteristics over those made of S4200. The SURGALLOY™ needles had considerably greater resistance to bending than the needle produced from the S4200 alloy. In addition, SURGALLOY™ stainless steel had almost a 2-fold greater resistance to fracture than the S4200 stainless steel alloy.

Every surgical needle has three basic components: swage, body, and point. For closure of skin wounds, we recommend laser-drilled needles.²⁵ Using laser-drilling, the needle is attached to the suture by uniformly compressing the walls of the swage against the suture, creating a strong attachment force that prevents the surgeon from detaching the suture from the needle without exerting considerable force on the swage. We prefer cutting edge needles that have at least two opposing edges designed to penetrate tissue. For skin closure, we recommend a reverse cutting needle that leaves a wide wall of tissue against which the suture exerts its wound closure force. This thick wall of tissue resists suture cut-through. In all surgical needles, we prefer that they are made from SURGALLOY™ stainless steel.²⁶

Continuous Percutaneous Skin Suture Closure

A small skin incision whose length is less than 5 cm is made with a No. 15 knife blade. The surgeon uses a reverse cutting edge needle with a subtended arc of 135° for continuous percutaneous skin closure using the VASCUFIL™ suture. Continuous percutaneous suture closure has definite, distinct advantages over interrupted suture closure. First, continuous suture closure can be accomplished more rapidly than interrupted suture closure. This time saving is related to the short time involved in constructing knotted suture loops. For the continuous suture closure, there is one knotted suture at each corner of the wound. In contrast, interrupted suture skin closure requires knot construction for each separate suture loop. Another advantage of the continuous suture is that it accommodates to the developing edema of the wound edges during healing. In contrast, the dimensions of

the interrupted suture loop remain unchanged, constricting the edematous tissue within each suture loop. These benefits of the continuous suture skin closure technique must be weighed against one notable disadvantage. Interrupted suture closure permits a more meticulous approximation of the wound edges than continuous suture closure, especially in stellate lacerations with irregular wound edges.

Continuous VASCUFIL™ percutaneous suture closure of the wound can be accomplished by two different techniques. In the first technique, the needle pathway is at a 90° angle to the wound edges and results in a visible suture that crosses the wound edges at a 65° angle. This technique is technically easier to accomplish than one in which the needle pathway is oblique to the wound edge. In the second technique, the needle pathway is at a 65° angle to the wound edges, so that the visible suture is at a 90° angle to the wound edges rather than at a 65° angle. This oblique passage of the needle is difficult to reliably replicate throughout a long incision. With either technique, the surgeon starts the continuous percutaneous suture with an interrupted percutaneous suture placed 1 mm from either end of the wound. The needle is passed in a direction toward the surgeon, rather than away from the surgeon. The exit and entrance points of this first interrupted percutaneous suture are 4 mm from the wound edges. After completion of the first percutaneous suture, construct a secure 3-throw square knot and cut the free suture ear 3 mm from the knot. Position the knot so that it lies at a point farthest from you. Holding the fixed suture end parallel to the wound, the needle should be passed through the skin 2 mm from and adjacent to the knot. This needle entrance site is 4 mm from the wound edge and 2 mm from the first interrupted percutaneous suture. Pass the needle beneath the skin at an angle 90° to the incision and exit 4 mm from the wound edge through the skin on the opposite side of the wound.

The next suture then crosses the wound at a 65° angle to the wound to an entrance point 4 mm from the wound edge. Again, the needle is passed beneath the wound at a 90° angle to the wound to continue placement of the suture. The passage of the suture is repeated as described until the wound edges are almost completely approximated by the continuous percutaneous suture, with one remaining needle pass necessary for complete repair. When the surgeon is at a point that is 2 mm from the end of the wound, pass your needle perpendicular to the wound through

the skin so that its entrance and exit points are 4 mm from the wound edge. This last needle passage traverses the wound at an angle of 90° to the incision. The continuous percutaneous suture ends as an interrupted percutaneous suture which is accomplished with care to leave a suture loop remaining during suture pull through; this suture loop will be used in knot construction.

Knot construction is accomplished using an instrument tie with the fixed end of the suture and the remaining suture loop. When constructing a secure knot with a suture loop and free suture, we prefer a six-throw square knot with 3 mm ears, rather than a three-throw knot, to ensure knot security.¹⁵ It is advisable to cut the needle from the fixed suture end with surgical scissors before performing the instrument tie.

Continuous Dermal Skin Suture Closure

Although continuous dermal wound closure is technically more challenging for the surgeon than interrupted dermal suture closure, it has become an important wound closure technique. It results in closely approximated wound edges that quickly become impervious to exogenous topical bacterial contamination. The use of a continuous dermal suture, without percutaneous sutures, is an attractive alternative for wound subjected to strong skin tensions, in patients prone to keloid formation, children frightened by suture removal, and those individuals who are unable to contact a health professional for suture removal.

Monofilament absorbable synthetic MAXON™ sutures, whose tensile strength remains for at least 28 days, are ideally suited for continuous dermal suture because they do not have to be removed. In contrast, the nonabsorbable dermal continuous suture has to exit percutaneously from the ends of the wound and must surface every 3 cm through the skin, along the length of the continuous suture, to facilitate removal. The 4-0 monofilament synthetic absorbable suture is attached to the laser-drilled hole of the reverse cutting edge needle.

Placement of a continuous dermal suture can be facilitated by first approximating the mid-portion of the wound with an interrupted synthetic absorbable suture. This suture serves to align accurately the divided edges of the wound as well as to restore the configuration of the wound edges before suture closure.

The continuous dermal suture is begun as an interrupted anchoring dermal suture by passing the needle in an upward direction, through the subcutaneous tissue and exiting through the reticular dermis at the apex of the wound. A secure five-throw square knot is constructed to secure the suture.

After cutting the one ear attached to the free suture end, the fixed suture end with attached needle is used for the continuous dermal skin closure. The next stitch is passed horizontally from the end of the wound through the superficial papillary dermis. After exiting the dermis, the position of the next bite is identified by pulling the suture across at right angles to the wound. Accurate needle placement is assured by slight back-tracking of each bite. By keeping each bite of the continuous dermal closure small, less than 3 mm, you can avoid puckering of the skin edges after closure, and subsequent malapposition of the wound edges. During passage of the needle, the skin is stabilized by the tissue forceps. As the small horizontal bites are taken, gentle constant traction of the fixed suture brings the wound edges together.

At a point one bite from the end of the wound, a small horizontal bite is passed toward the end of the wound. The suture before this corner stitch is withheld, forming a loop for the free end of the suture that will be used in constructing the knot. After passing the suture horizontally through a small bite of dermis in the opposite wound edge, the fixed suture end and the long loop of the free suture end are used to construct a secure six-throw square knot.²⁷

It is important to note that the knot may not remain buried in the subcutaneous tissue using this technique. Consequently, some surgeons cut only the suture loop flush with the knot. They then bury the knot by passing the fixed end of the suture attached to the needle proximal to the knot at the apex of the wound at the level of the subcutaneous tissue, exiting through the skin approximately 5 mm from the end of the wound. As the surgeon exerts tension on the fixed suture end after needle passage through the skin, this movement inverts the knot into the subcutaneous tissue. While maintaining tension on the fixed suture end, the suture is cut flush with the skin. The cut suture disappears from the surgeon's view, retracting into the subcutaneous tissues. It is important to note the exact technique of suture passage that is required for knot inversion. If the fixed suture end with its attached needle is passed distal to the knot at

the apex of the wound, this maneuver will serve to evert the knot into the wound. In the human, the skin edges are then approximated by percutaneous tape closure to ensure a meticulous approximation of the wound edges.

Conclusion

Your success in achieving optimal wound closure using sutures and their attached needles will depend on several factors. First, you must have all of the appropriate sutures and attached needles that are necessary to achieve wound closure. Inadequate instruments will defeat the efforts of even the master surgeon. Second, mastery of surgical skills using sutures and needles requires repetitive practice. Surgeons who do not have adequate psychomotor skills will not achieve an excellent result even with the finest sutures and their attached needles. Third, select the most appropriate sutures with their attached needles based on the biology of wound repair and infection and the biomechanics of sutures and needles. Finally, you must always use a double-glove hole indication system that accurately detects holes in the gloves. In the event of a needlestick exposure during surgery, operating personnel must follow carefully the post-exposure prophylaxis plan against bloodborne deadly viral infections outlined in this course. As you perfect your surgical discipline, share this information with your colleagues and encourage them to participate in a training program. In addition, we encourage each of you to evaluate carefully the clinical results of your wound closure with sutures and strive to devise new and improved techniques that are based on scientific investigations rather than testimonials.

It has been recently announced that there is a revolutionary knotless technology that supports optimal patient outcomes by closing wounds securely. This V-Loc™ 180 device closes wounds up to 50% faster than conventional sutures with comparable holding strength.²⁸ This novel suture construct has been developed to prevent the need for knot laparoscopic suture. Self-anchoring, unidirectional barbs in the suture allow secure tissue apposition with continuous suture without the need to tie knots. Barb suture material has been used clinically on a limited basis in dermal closure, orthopedics, and urology.²⁸ This V-Loc suture is produced from a size 0 polydioxanone monofilament that absorbs within 26 weeks.

References

1. Thacker JG, Rodeheaver G, Kurtz L, Edgerton MT, Edlich RF. Mechanical performance of sutures in surgery. *Am J Surg.* 1977; 133:713-715.
2. Trimbos JB. Security of various knots commonly used in surgical practice. *Obstet Gynecol.* 1984; 64:274-280.
3. Ellis H. The hazards of surgical glove dusting powders. *Surg Gynecol Obstet.* 1990; 171:521-527.
4. Kelly KJ, Walsh-Kelly CM. Latex allergy: A patient and health care system emergency. *Ann Emerg Med.* 1998; 32:723-729.
5. Edlich RF, Wind TC, Heather CL, Thacker JG. Reliability and performance of innovative surgical double-glove hole puncture indication systems. *J Long Term Eff Med Implants.* 2003; 13(2):63-83.
6. Edlich RF, Wind TC, Heather CL, Degnan GG, Drake DB. Recommendations for post-exposure prophylaxis of operating room personnel and patient's exposed to blood borne diseases. *J Long Term Eff Med Implants.* 2003; 13: 103-116.
7. Levenson SM, Greever EF, Crowley LV. The healing of rat skin wounds. *Ann Surg.* 1965; 161: 293-308.
8. Adamsons RJ, Kahan SA. The rate of healing of incised wounds of different tissues in rabbits. *Surg Gynecol Obstet.* 1970; 130: 837-846.
9. Van Winkle W Jr., Hastings JC, Barker E, Hines D, Nichols W. Effect of suture materials on healing skin wounds. *Surg Gynecol Obstet.* 1975; 140:7-12.
10. Forrester JC. Collagen morphology in normal and wound tissue. In: *Wound Healing and Wound Infection: Theory and Surgical Practice.* (Ed.) Hunt JK, Appleton-Century-Crofts, New York, NY, 1980; p 118-134.
11. Botsford TW. The tensile strength of sutured skin wounds during healing. *Surg Gynecol Obstet.* 1941; 72:690-697.
12. Madden JW, Smith HC. The rate of collagen synthesis and deposition in dehisced and resutured wounds. *Surg Gynecol Obstet.* 1970; 130: 487-493.
13. Dunphy JE, Jackson DS. Practical applications of experimental studies in the care of the primarily closed wound. *Am J Surg.* 1962; 104:273.
14. Edlich RF, Rogers W, Kasper G, Kaufman D, Tsung MS, Wangenstein OH. Studies in the management of the contaminated wound: I. Optimal time for closure of contaminated open wounds: II. Comparison of the resistance to infection of open and closed wounds during healing. *Am J Surg.* 1969; 117: 323- 329.
15. Postlethwait RW. Long-term comparative study of non-absorbable sutures. *Ann Surg.* 1970; 171: 892-898.

16. Rodeheaver GT, Nesbit WS, Edlich RF. Novafil. A dynamic suture for wound closure. *Ann Surg.* 1986; 204:193-199.
17. Rodeheaver GT, Shimer AL, Boyd LM, Drake DB, Edlich RF. An innovative absorbable coating for the polybutester suture. *J Long Term Eff Med Implants.* 2001; 11(1&2):41-54.
18. Salthouse TN, Williams JA, Willigan DA. Relationship of cellular enzyme activity to catgut and collagen suture absorption. *Surg Gynecol Obstet.* 1981; 129:691-696.
19. Rodeheaver GT, Thacker JG, Edlich RF. Mechanical performance of polyglycolic acid and polyglactin 910 synthetic absorbable sutures. *Surg Gynecol Obstet.* 1981; 153:835-841.
20. Faulkner BC, Gear AG, Hellewell TB, Mazzarese PM, Watkins FH, Edlich RF. Biomechanical performance of a braided absorbable suture. *Surg Gynecol Obstet.* 1981; 153:497-507.
21. Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surg Gynecol Obstet.* 1985; 161:213-222.
22. Rodeheaver GT, Beltran KA, Green CW, Faulkner BC, Stiles BM, Stanimir GW, Traeland H, Fried GM, Brown HC, Edlich RF. Biomechanical and clinical performance of a new synthetic monofilament suture. *J Long Term Eff Med Implants.* 1996; 6: 181-196.
23. Edlich RF, Thacker JG, McGregor W, Rodeheaver GT. Past, present and future for surgical needles and needle holders. *Am J Surg.* 1993; 166:522-532.
24. Watkins FH, London SD, Neal JG, Thacker JG, Edlich RF. Biomechanical performance of cutting edge surgical needles. *J Emerg Med.* 1997; 15: 679-685.
25. Ahn LC, Towler MA, McGregor W, Thacker JG, Morgan RF, Edlich RF. Biomechanical performance of laser-drilled and channel taper point needles. *J Emerg Med.* 1992; 10:601-606.
26. Thacker JG, Borzelleca DC, Hunter JC, McGregor W, Rodeheaver GT, Edlich RF. Biomechanical analysis of needle holding security. *J Biomed Mat Res.* 1986;20:903-917.
27. Annuziata CC, Drake DB, Woods JA, Gear AJ, Rodeheaver GT, Edlich RF. Technical considerations in knot construction. Part I. Continuous percutaneous and dermal suture closure. *J Emerg Med.* 1997; 15:351-356.
28. Demyttenaere SV, Nau P, Henn M, Beck C, Zaruby J, Primavera M, Kirsch D, Miller J, Liu JJ, Bellizzi A, Melvin WS. Barbed suture for gastrointestinal closure: a randomized control trial. *Surg Innov.* 2009; 16(3):237-242.

Scientific Basis for the Selection of Vascular Closure Techniques

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If this educational program heightens the surgeon's, resident's, and student's interest in the biology of vascular wound closure and infection, the long years occupied in our search for improved methods of wound management would more than fulfill our expectations. As with any master surgeon, he/she must understand the tools of his/her profession. This linkage between a surgeon and surgical equipment is a closed kinematic chain in which the surgeon's power is converted into finely coordinated movements that result in vascular wound closure with the least possible scar and without infection. The description of wound repair of blood vessels will be confined to arterial surgery in which the surgeon attempts to establish a new non-wettable intima and to reestablish a strong elastic muscular media. Repair of vessel wall wounds is encountered in arteriotomy for vascular access as well as in artery-to-artery anastomoses. In both circumstances, wound repair is primarily at the suture line. The surgical needles of Syneture™ are produced from stainless steel alloys, which have excellent resistance to corrosion. A new high-nickel stainless steel, SURGALLOY™, has been used recently by Syneture™ to manufacture surgical needles. We prefer a polybutester monofilament suture whose surface is coated with an absorbable polymer. This absorbable coating of the VASCUFIL™ monofilament sutures markedly reduces its drag forces in vascular tissue. The surgeon can practice using these sutures in femoral arteriotomies in animals.

KEY WORDS: vascular suture repair, SURGALLOY™ taper point needles, VASCUFIL™ suture, femoral arteriotomy

Introduction

If this educational program heightens the surgeon's, resident's, and student's interest in the biology of vascular wound closure and infection, the long years occupied in our search for improved methods of wound management would more than fulfill our expectations. Through the ages, selection of surgical sutures, needles and gloves has been an important consideration for surgeons. Despite these important historical considerations, some surgeons perceive surgical suture, needle and glove selection more as an art than as a science. For those artisans, the use of methods and materials for suturing and glove selection is usually a matter of habit, guesswork, or tradition. This approach to suturing has contributed to a growing concern that the suture selection as well as knot tying techniques employed by many surgeons is not optimal, and that they incorrectly select sutures and use faulty techniques in tying knots, which is the weakest link in a tied surgical suture. When the recommended configuration of a knot ascertained by mechanical performance tests was compared to those used by board-certified general surgeons, only 25% of surgeons used the appropriate knot construction.¹ Of the twenty-five gynecologists, mostly department heads, who were polled about their knot tying technique, most were convinced that they made square knots, even though their knot-tying techniques resulted in slipped knots that became untied.² When a knotted suture fails to perform its functions, the consequences may be disastrous. Massive bleeding may occur when the suture loop surrounding a vessel becomes untied or breaks. Wound dehiscence or incision hernia may follow knot disruption. As with any master surgeon, he/she must understand the tools of his/her profession. This linkage between a surgeon and surgical equipment is a closed kinematic chain in which the surgeon's power is converted into finely coordinated movements that result in vascular wound closure with the least possible scar and without infection.

Fortunately, surgeons have transformed surgical suture and needle selection from a ritual practice to a surgical discipline. Early in their careers, surgical selection of sutures and needles was largely based on testimonials and anecdotal experiences of senior surgeons. Today, modern surgeons select sutures and needles on the basis of well-controlled, randomized clinical and experimental trials in vascular surgery.

Biology of Vascular Repair

The description of wound repair of blood vessels will be confined to arterial surgery in which the surgeon attempts to establish a new non-wettable intima and to reestablish a strong elastic muscular media. There are four possible origins of neoendothelial cells after injury: (1) circulating macrophage mononuclear cells; (2) medial smooth muscle cells; (3) circulating endothelial cells; and (4) junctional zone, which are graft/post pannus extension of the anastomosis. The origin of the new elastic fibers for the subintimal elastic lamina is the medial smooth muscle (myointimal) cells. The biology of the vessel healing can be divided into three phases: substrate, proliferative, and resorptive (maturation).³ The substrate phase lasts three to four days. During the initial two to three days, fibroblasts appear in the wound and begin producing collagen shortly after their appearance. The substrate phase is overlapped by the proliferative phase where the collagen is laid down in the wound. By the fifth or sixth day, new collagen synthesis accelerates, and wound strength enhances quickly. The proliferative phase continues for several weeks. The process of wound repair becomes a balance between the synthesis of collagen and the lysis of collagen. Imbalance of lysis and repair results in a failure of wound healing. In one case, excessive collagen lysis will result in anastomotic failure. In contrast, excessive collagen production may result in stricture formation. In the resorptive phase, tissue macrophages and fibroblasts disappear and excess collagen is removed. During this phase of absorption, the amorphous mass of collagen is transformed into an interlocking connection of collagen fibers. Blood vessels contain a special type of collagen (type III) that possesses special properties that allow some elasticity of the collagenous tubing, thereby enhancing its performance as a vascular conduit. Wound repair will now be examined in vessel wall wounds.

Repair of vessel wall wounds is encountered in arteriotomy for vascular access as well as in artery-to-artery anastomoses. In both circumstances, wound repair is primarily at the suture line. Both of these surgical procedures are usually performed in areas of relatively normal arteries that augur for the best wound repair. It is important to point out that the endothelium of artery-to-artery anastomoses and arteriotomies heal by pannus extension that is continuous autogenous endothelial growth

across a suture line, rather than by cellular ingrowth from within the lumen of the vessel. Humans are able to extend an endothelial pannus for only 6 to 10 mm in either direction from the suture line. Replacement of this endothelial cell layer is rapid and likely to be complete in ten days. Orientation of the new endothelial cells appears random. By twenty-one days, the endothelial cells resume their normal orientation that is parallel to the blood flow. Regeneration of the elastic lamina is not rapid or as successful as endothelial repair. The elastic lamella defect is repaired by four or six weeks. The origin of the new elastic fibers is from medial smooth muscle cells. Collagen synthesis begins to exceed lysis and suture line strength begins to enhance within three to four weeks.⁴ On the basis of these observations, surgeons recommend that stress on the anastomosis or arteriotomy should be kept at a minimum for at least two weeks.

The growth of the vascular suture line has been studied extensively in a large number of experiments. Although some felt that body growth ultimately resulted as light relative stenosis at the suture line, all investigations reported that the suture lines grew fairly well as the parent artery increased in size. However, it was evident that the tendency toward constriction at the suture line was considerable if continuous nonabsorbent sutures were employed. Moreover, constriction was minimized by the use of continuous monofilament absorbable suture or interrupted nonabsorbent suture. Consequently, it is generally agreed that in infant and growing children, vascular anastomotic repair can be accomplished by two different techniques to avoid late anastomotic stenosis. In one technique, one half of any anastomosis with nonabsorbable suture should be made with interrupted sutures.⁵ In the other technique, a continuous monofilament absorbable suture can be used clinically with a low incidence of stenosis.⁶ Some surgeons use monofilament synthetic absorbable suture for anastomosis repair in infants and growing children. When surgeons make tucks under the suture line, these tucks may result in disruption of the laminar flow and may lead to progressive stenosis of suture repair. Finally, in an adult, the surgeon should use at least reactive nonabsorbable suture, monofilament polypropylene, because this suture maintains anastomotic strength, causes the least fibrosis of the suture line and facilitates a more rapid resolution of the suture line inflammatory response.

There has been some debate regarding the various types of suture techniques. On the basis of their investigations, Schumacker and Lowenberg concluded that mattress suture techniques were preferable to techniques into which an end-on approximation of the artery was accomplished by a continuous suture.⁷ However, Sako and colleagues reported no essential difference in the incidence of thrombosis with the mattress technique and with suture passed through all layers.⁸ Opinions remain somewhat divided as to the relative merits of the mattress suture and the end-on approximation. The ease with which end-on approximation can be accomplished has caused most surgeons to rely exclusively on the continuous end-on approximation technique. Lowenberg and Shumacker conducted further studies on the healing characteristics of divided and then sutured carotid arteries in dogs.⁹ The breaking strength at the anastomotic site was evaluated with the original silk suture intact. The same type of healing curve was observed as had been established by similar experiments for the healing of other tissues, such as the abdominal wall. It was concluded that arteries gained strength much in the same fashion as did all other tissues which had been studied. The actual force, which disrupted the recently sutured artery during the "lag" period, was as little as 2 lbs. It was evident that a small force at that time could pull apart a recently completed arterial anastomosis and that it was important to approximate blood vessels without tension. Their observations indicated that while the force necessary to break the recently sutured artery by direct pull was not great, the sutured artery rapidly regained resistance to intraluminal pressures, and that after 14 days or longer, could withstand, without leaking, intraluminal pressures in excess of normal systolic blood pressure. Preliminary studies by these authors demonstrated that the circumference of the artery at the anastomosis increased in the growing animal comparable to the increase in the circumference of the unsutured portion of the artery. The investigators pointed out that many of the healed suture lines failed to break or burst at pressures that ruptured the artery itself.

Scientific Basis for Selecting Vascular Surgical Needles and Sutures

The surgical needles of Syneture™ are produced from stainless steel alloys, which have excellent re-

sistance to corrosion. A new high-nickel stainless steel, SURGALLOY™, has been used recently by Syneture™ to manufacture surgical needles. Studies have demonstrated that the SURGALLOY™ needles have considerably more resistance to bending than the needle grooves from the S45500 alloy. Consequently, we recommend using taper point needles made from SURGALLOY™ for vascular surgical repair. We prefer a polybutester monofilament suture whose surface is coated with an absorbable polymer. This absorbable coating of the VASCUFIL™ monofilament sutures markedly reduces its drag forces in vascular tissue. The surgeon can practice using these sutures in femoral arteriotomies in animals.

There are two important considerations in making vascular incisions: the direction of the incision and the manner of the closure. Longitudinal incisions provide excellent exposure because they can be easily extended. This benefit must be weighed against a distinct disadvantage. Closure of a longitudinal incision in smaller (< 4 mm) vessels narrows the lumen over a great distance and thereby causes significant stenosis and turbulence that may lead to thrombosis. This narrowing is not encountered in closure of a transverse incision. Consequently, a transverse arteriotomy is recommended in smaller vessels.

Continuous suture closure of longitudinal arteriotomy

The chosen area for the femoral arteriotomy is exposed, mobilized, and isolated. Partial occlusion of the artery by two silicone loops is not undertaken until everything is ready for the arteriotomy, thereby minimizing the occlusion time. The silicone loops are now positioned at sites proximal and distal to the planned arteriotomy. Sufficient tension is applied to the ends of the suture loops to temporarily obstruct the flow of blood into the artery. Tension is applied first to the ends of the silicone loops to occlude partially the vessel lumen. Both ends of the silicone loops are then clamped between silicone-covered jaws that maintain vessel occlusion.

The longitudinal arteriotomy is initiated with a short opening of the lumen with the cutting edge of a No. 11 blade, rather than its point. The arteriotomy is then completed by cutting the vessel wall with a 7-inch DeBakey vascular scissors whose jaws are positioned at a 45° angle to the scissor handles. The length of the longitudinal arteriotomy is 3 cm long.

In this psychomotor skill station, the arteriotomy will be closed with a continuous VASCUFIL™ suture. A 36-inch-length 4-0 VASCUFIL™ double-armed suture swedged to taper point needles with subtended arcs of 180° is used for continuous sutural closure of the arteriotomy. This needle is grasped between the smooth jaws with rounded edges of the T-C Crile Wood needle holder 1.5 mm beyond the end of its laser-drilled hole. The surgeon begins the arteriotomy closure at the proximal end of the arteriotomy farthest from the surgeon. The vessel wall is everted with the 6-inch-long smooth DeBakey forceps to permit needle passage through the intima and overlying vessel wall 1 mm lateral to the end of the arteriotomy. With eversion of the opposite wall, the needle is passed through the intima and overlying vessel wall 1 mm lateral to the arteriotomy. Using an instrument tie, a three-throw square knot is constructed. After knot construction, the knot is positioned at a point farthest away from the surgeon. One fixed suture end with attached needle is cut 3 mm from the knot, leaving one 3-mm knot ear. The other fixed suture end attached to the needle is then passed through the adventitia and intima at a point 1 mm from the last interrupted suture and 1 mm from the divided vessel edge.

The needle is then passed out through the intima and overlying vessel wall 1 mm from the vessel edge on the opposite side of the arteriotomy. The sutural closure is then continued with similarly positioned sutures 1mm from each other and 1mm from the divided vessel wall perpendicular to the suture line. The polypropylene suture must be pulled taut continuously to maintain approximation of the vessel wall and avoid later suture line bleeding. A fine nerve hook with a blunted point inserted through the end of the arteriotomy can be used as a safeguard as the final suture is passed. At this point, tension is released from the proximal suture loop, allowing blood and air to escape from the remaining opened end of the longitudinal arteriotomy.

After passing the final suture 1 mm lateral to the end of the arteriotomy, knot construction is accomplished with the suture loop and free suture ends using a six-throw square knot construction. The suture loop and ear are cut 3 mm from the knot, leaving three, 3-mm-long suture ears.

Tension is now removed from the distal silicone loop, allowing blood flow to return to the femoral artery. When closing a longitudinal incision in small (4

mm diameter) vessels, stenosis of the approximated lumen will occur with a continuous suture. This stenosis may be obviated by the insertion of an elliptical vein graft.

The surgeon's ultimate selection of surgical sutures and needles will be dependent on his/her perception of the performance of the suture and needle during surgery. Realizing the importance of understanding the surgeon's perception of the performance of suture and needle products, two large multicentric evaluations of suture and needle products have been reported in peer-reviewed publications.^{10, 11} The guidelines used in the development of this multicentric evaluation of surgical suture and needle products should be replicated in any hospital setting to assure that the surgeon has a superior needle and suture product.

The purpose of this initial report was to describe an expanded suture and needle clinical evaluation program jointly designed by hospital representatives of Consorta, Inc. (Rolling Meadows, Illinois), a leading healthcare resource management and group purchasing organization, and Syneture™ Sutures (division of Covidien Inc., Norwalk, CT).¹⁰ In this expanded evaluation program, 42 Consorta shareholder hospitals enrolled 1913 surgeons to participate in Phase II of this nonexperimental observational study of the clinical performance of surgical needles and sutures. Performance characteristics of the sutures and needles produced by Syneture™ Sutures that were evaluated in 25,545 surgical procedures included packaging/ease of opening, needle strength and sharpness, tissue drag, knot security, tensile strength, clinically acceptable determinations, and clinically unacceptable determinations. In these 30-day studies, the surgeons found that the needles and sutures were clinically acceptable in 98.1% of the evaluations. The general, cardiothoracic, and orthopedic surgeons who performed 61.2% of the product evaluations reported that the suture and needle products were clinically acceptable in 98.2% of the evaluations. Nearly half (49.2%) of the evaluations involved the POLYSORB™ braided synthetic sutures, which received a clinically acceptable rating in 98.2% of the evaluations. The silk suture (SOFILK™), followed by the monofilament nylon suture (MONOSOF™), were the next most frequently used sutures. The SOFSILK™ was found to be clinically acceptable in 99.2% of the evaluations, while MONOSOF™ was noted to be clinically acceptable in 98.7% of the

evaluations. Surgical needles made by Syneture™ Sutures also had a high rating of clinical acceptability (97.9%).

This second report described an innovative suture and needle clinical evaluation program jointly designed by hospital representatives of Consorta, Inc., a healthcare resource management and group purchasing organization, and Syneture™ Sutures (division of Covidien Inc., Norwalk, CT), manufacturer of surgical biomaterials.¹¹ Nineteen Consorta shareholder hospitals enrolled 699 surgeons to participate in Phase I of this nonexperimental observational study of the clinical performance of surgical needles and sutures. Performance characteristics of the sutures and needles produced by Syneture™ Sutures, which were evaluated in 3407 surgical procedures, included packaging and ease of opening, needle strength and sharpness, tissue drag, knot security, tensile strength, and clinically acceptable and unacceptable determinations. In these 30-day studies, the surgeons concluded that the needles and sutures were clinically acceptable in 98.1% of the evaluations. The general, cardiothoracic, and orthopedic surgeons, who performed 73.8% of the product evaluations, reported that the suture and needle products were clinically acceptable in 97.2% of the evaluations. More than half (50.1%) of the evaluations involved the POLYSORB™ braided synthetic sutures, which received a clinically acceptable rating in 98.4% of the evaluations. The next most frequently used sutures were the SOFSILK™, followed by the monofilament nylon suture. SOFSILK™ was found to be clinically acceptable in 98.7% of the evaluations, whereas the monofilament nylon was noted to be clinically acceptable in 96.3% of the evaluations. Surgical needles made by Syneture™ Sutures had a 97.9% clinical acceptability rating.

Discussion

Your success in achieving optimal wound closure using sutures and their attached needles will depend on several factors. First, you must have all of the appropriate sutures and attached needles that are necessary to achieve wound closure. Inadequate instruments will defeat the efforts of even the master surgeon. Second, mastery of surgical skills using sutures and needles requires repetitive practice. Surgeons who do not have adequate psychomotor skills will not achieve an excellent result even with the finest sutures and

their attached needles. Third, select the most appropriate sutures with their attached needles based on the biology of wound repair and infection and the biomechanics of sutures and needles. Finally, you must always use a double-glove hole indication system that accurately detects holes in the gloves.¹² In the event of a needlestick exposure during surgery, operating personnel must follow carefully the post-exposure prophylaxis plan against bloodborne deadly viral infections. As you perfect your surgical discipline, share this information with your colleagues and encourage them to participate in this training program. In addition, we encourage each of you to evaluate carefully the clinical results of your wound closure with sutures and strive to devise new and improved techniques that are based on scientific investigations rather than testimonials.

References

1. Thacker JG, Rodeheaver G, Kurtz L, Edgerton MT, Edlich RF. Mechanical performance of sutures in surgery. *Am J Surg.* 1977;133:713-715.
2. Trimbos JB. Security of various knots commonly used in surgical practice. *Obstet Gynecol.* 1984;64: 274-280.
3. Gaylis H, Corvese WP, Linton RR, Shaw RS. The rate of healing of arterial autografts. *Surgery.* 1959;45: 41-58.
4. Tawes RL, Aberdeen E, Berry CL. The growth of an aortic anastomosis: an experimental study in piglets. *Surgery.* 1968;64:1122-1132.
5. Reed MK, Lowry PA, Myers SI. Successful repair of pediatric popliteal artery trauma. *Am J Surg.* 1990;160:287-290.
6. Hawkins JA, Minich LL, Tani LY, Ruttenburg HD, Sturtevant JE, McGough EC. Absorbable polydioxanone suture and results in total anomalous pulmonary venous connection. *Ann Thorac Surg.* 1995;60 :55-59.
7. Shumaker HB, Lowenberg RI. Experimental studies in vascular repair. I. Comparison of reliability of various methods of end-to-end arterial sutures. *Surgery.* 1948;24:79-89.
8. Sako Y, Chisholm TC, Varco RC, Merendino KA. An experimental evaluation of certain methods of suturing the thoracic aorta. *Ann Surg.* 1949; 130: 363-383.
9. Lowenberg RI, Shumacker HB Jr. Experimental studies in vascular repair. I. Strength of arteries repaired by end-to-end suture, with some notes on growth of anastomoses in young animals. *Arch Surg.* 1954;139:439.
10. Szarmach RR, Livingston J, Rodeheaver GT, Thacker JG, Edlich RF. An innovative surgical suture and needle evaluation and selection program. *J Long Term Eff Med Implants.* 2002;12(4):211-229.
11. Szarmach RR, Livingston J, Edlich RE. An expanded surgical suture and needle evaluation and selection program by a healthcare resource management group purchasing organization. *J Long Term Eff Med Implants.* 2003;13(3):155- 170.
12. Edlich RF, Wind TC, Heather CL, Thacker JG. Reliability and performance of innovative surgical double-glove hole puncture indication system. *J Long Term Eff Med Implants.* 2003;13(2):69-83.

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