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WRIST FUSION:
Fighting back against rheumatoid arthritis

Debbie Uchida, CST

Rheumatoid arthritis, commonly known as RA, affects more than 2 million people in the United States annually. The disease affects more women than men and typically develops between the ages of 25 and 50. It is a chronic, inflammatory, autoimmune disease that causes the immune system to attack the joints. It can be a very painful and disabling condition that can lead to substantial loss of mobility due to joint destruction.3

LEARNING OBJECTIVES

- Compare and contrast treatment options of rheumatoid arthritis
- Evaluate the advantages and disadvantages of wrist fusion as treatment for arthritis
- Summarize the steps of a wrist fusion procedure
- Distinguish the different categories of arthritis drugs
- Compare and contrast wrist fusion and wrist replacement
While RA is not inherited, genes that may make an individual more likely to develop the disease can be inherited. Researchers continue to work to discover what roles genes may play in developing the condition. It is important to note that there is no known cause for the disease.

While pharmaceutical options can temporarily curb the onset of RA, surgery is also an option. Surgical fusion, sometimes called arthrodesis, has a high success rate in patients with advanced cases of RA. Arthrodesis comes from the words “arthro,” or joint, and “desis,” or binding.

**DIAGNOSING RA**

The first step in diagnosing the disease is meeting with a rheumatologist, who specializes in rheumatoid diseases, including detecting signs and symptoms of certain types of arthritis. Diagnosis begins with reviewing family history, examining joints for inflammation and deformity, and the skin for rheumatoid nodules, firm, nontender, subcutaneous nodules, which usually occur in chronic active cases of RA. They are commonly associated with more joint deformity and serious extra-articular manifestations, including lungs, eyes and blood vessels. Certain blood tests and X-rays are often common steps in the diagnosis, which is based on the pattern of symptoms, distribution of the inflamed joints and the blood and X-ray findings. X-rays can show bony erosions typical of RA in the joints. Joint X-rays can also be helpful in monitoring the progression of the disease and joint damage over time.

Abnormal blood antibodies, specifically rheumatoid factor, is found in 80 percent of RA patients. Citrulline antibody is also present in most patients with RA. It is useful in the diagnosis of the disease when evaluating patients with unexplained joint inflammation.

An arthrocentesis may also aid in diagnosis. In this procedure, a sterile needle and syringe are used to drain joint fluid for laboratory testing. Analysis of the joint fluid can help exclude other causes of arthritis, such as infection or gout.

**ANATOMY OF THE WRIST**

The wrist is a collection of many bones and joints, making it one of the most complex joints in the entire body. These bones and joints allow us to use our hands in many ways. The wrist must be extremely mobile to give our hands full range of motion. The metacarpal bones are the long bones in the palm and are connected to the phalanges, the bones in the fingers and thumb. Eight carpal bones, arranged in two rows, compose the anatomy of the wrist joint. The carpal bones connect the two bones of the forearm, the radius and the ulna, to the bones of the hand. The distal row proceeding from the radius to the ulnar side includes the trapezium, trapezoid, capitate and hamate. The proximal row consists of the scaphoid, lunate, traquetrium and pisiform. Functionally, the scaphoid links the rows as it stabilizes and coordinates the movement of the proximal and distal rows. (Figure 1)

**RHEUMATOID DISEASE OF THE WRIST**

RA of the hand and wrist principally affects the synovial lining of joints and tendon sheaths. As it progresses, the disease process invades and destroys ligaments and tendons. Intrinsic contracture, a crippling process, develops during the early, acute inflammatory stage. The synovial disease may directly invade the tendons, which become frayed, fragile, attenuated or weakened and can potentially rupture, although rupture is more likely when boney compression and friction occur. This process within the wrist joint invades and destroys the supportive ligaments and capsules. The disease can extend into the distal radioulnar joint (DRUJ), which becomes fixed in pronation, and the lower end of the ulna is subluxed dorsally, making rotary motion painful.

Although it is desirable to avoid surgery on the wrist joint during a period of heightened activity, delay in the face of rampant disease is inadvisable.
Symptoms of RA in the wrist joint include pain, swelling, muscle cramping, stiffness at rest and feeling of weakness, especially after extensive use. Numbness to the areas surrounding the metacarpals and phalanges may also occur if swelling is persistent.

**Conservative Treatment for RA**

RA of the hand and wrist is part of a generalized disease that requires medical treatment. It is important to remember that managing the disease process is critical. Alternatives to surgery may begin with medical treatment prescribed by a rheumatologist or an orthopedic surgeon. Fast-acting “first-line drugs,” such as methylprednisolone acetate, cortisone and aspirin, are prescribed to reduce pain and inflammation. Slow acting “second-line drugs,” such as gold salts, methotrexate and hydroxychloroquine, promote remission and prevent progressive joint destruction. Newer prescription drug treatments include etanercept, adalimumab, infliximab and rituximab. These drugs are prescribed based on the severity of the patient’s condition.\(^7\)

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**Figure 1.**

![Diagram of the hand and wrist bones](image-url)
Proper regular exercise is important in maintaining joint mobility and strengthening the muscles around the joint. Eating a well-balanced diet is also an easy way to help keep the disease under control.

**Surgical Treatment, Including Fusion**

Although it is desirable to avoid surgery on the wrist joint during a period of heightened activity, delay in the face of rampant disease is inadvisable. Procrastination allows further degeneration of secondary joints, articular destruction and muscle and capsular contracture.

Most joints are made up of only two bones that require fusion; however, the wrist is somewhat different because of the complexity of the joint. A successful fusion involves several bones. The goal of a wrist fusion is to get the radius to fuse into one long bone that connects the carpal bones of the wrist and the metacarpals of the hand. Fusing the bones together can prevent further deformity, eliminate pain and improve alignment.

If the ulna is not fused, the patient will have continued rotation in the hand. However, with a fused wrist, the patient will not be able to bend the wrist after the operation.

**Case Study with Rationale for a Surgical Wrist Fusion**

The subject in this case study was diagnosed with RA at 26-years old. She underwent a right knee arthroscopy for complete synovectomy in April 1999, and a left wrist arthroscopy in December 2002, for severe rheumatoid disease with radiocarpal, midcarpal and DRUJ involvement. After a flare-up in 2005, radiographic evidence showed significant joint destruction in the left wrist. The subject opted for a wrist fusion.
procedure to stop further destruction of the joint. The surgery took place on December 1, 2006.

Procedural overview
The patient is taken to the operating room, placed in the supine position and given a general anesthetic. In this case, the left arm is prepped, draped with a tourniquet, and a time out is performed.

A dorsal, longitudinal incision is made and centered over the Lister tubercle, extending along the middle finger metacarpal, and proximally over the distal forearm. A dissection is made down the extensor retinaculum. An incision is then made down into the third compartment and dissection continues down through the capsule and the second and third compartments are elevated radially and ulnarily, respectively. The radiocarpal joint is then opened.

In this case, the metacarpal and radiocarpal joints were extremely involved with active synovium, so a synovectomy was performed. Dissection continued along the middle finger carpal metacarpal (CMC). The CMC joint was debrided, as were the capitate, lunate, scaphoid-capitate, radioscaphoid and radiolunate joints. A high-speed burr was used to debride the distal radius. The lunate bone was very necrotic and fragmented. A bone graft was taken from the Lister tubercle in the distal radius and placed in the midcarpal and radiocarpal joints.

A standard bend, Synthes wrist fusion titanium plate was fixed distally, first to the middle finger metacarpal and then proximally to the radius. The wrist was placed in five degrees of ulnar deviation and five degrees of extension based on the bend of the plate. A surgery-directed fluoroscopy confirmed positioning of the plate clinically and radiographically. Screws were then placed and measured. Once the plate was fixed and the wrist was fused, the distal ulna was addressed (Figure 3).

The ulnar head was extremely synovitic and had sharp ridges. A distal ulnar resection was deemed
necessary because of the synovitis and instability of the DRUJ. The resection was performed using an oscillating saw. The distal ulna was stabilized using local tissue and 3-0 braided nylon suture to imbricate the distal stump of the ulna.

The ulnar head that was removed was used as bone graft in the fusion site, and the wound was irrigated thoroughly. The tourniquet was deflated and bleeding was controlled.

The extensor retinaculum was reapproximated, leaving the extensor pollicis longus (EPL) tendon transposed. The wound was closed with 4-0 polyglactin 910, and 5-0 nylon. A light dressing and volar splint were applied. The patient was taken to the recovery room without apparent complications.1

CONCLUSION
The goal of a wrist fusion is to halt progression of the disease, relieve pain, provide stability and preserve mobility. Wrist fusion gives patients a stronger wrist for gripping. Regaining strength is especially important to young patients whose work involves intense activities using their hands.

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What if surgery isn’t the answer?

If surgery is an impractical response to a particular case of arthritis, other, more traditional methods of treatment are available. Prescription drugs have long been considered a primary treatment option for those with chronic arthritis symptoms. Since an individual’s response to drugs can vary, and because potential side effects and adverse reactions are also factors, finding the most effective combination of arthritis drugs can be a more difficult process than one might expect. Patients should become knowledgeable about the various arthritis drugs so they can make informed decisions with their doctor.

**NSAIDs / COX-2 Inhibitors**
Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most commonly prescribed and widely-used arthritis drugs. There are three types of NSAIDs: salicylates, traditional NSAIDs and Cox-2 selective inhibitors.1

**How they work**
Prostaglandins are a related family of compounds that are produced by the cells of the body and have several important functions, including promoting inflammation, pain and fever. They also facilitate the function of blood platelets and protect the stomach lining from the effects of acid. Prostaglandins are produced in the body’s cells by the enzyme cyclooxygenase (Cox). There are actually two Cox enzymes, Cox-1 and Cox-2, both of which produce prostaglandins that promote inflammation, pain and fever. However, only Cox-1 produces prostaglandins that support platelets and protect the stomach. NSAIDs block the Cox enzymes and reduce prostaglandins throughout the body. Consequently, ongoing inflammation, pain and fever are reduced. However, since the prostaglandins that protect the stomach and support the platelets and blood clotting also are reduced, NSAIDs can cause ulcers in the stomach and promote bleeding.2

**DMARDs**
Disease-modifying anti-rheumatic drugs (DMARDs), sometimes called “slow-acting anti-rheumatic drugs,” or “second-line agents,” can take weeks or months to work and are typically only administered after other treatments have failed. However, research has shown the effectiveness of DMARDs in the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis and the importance of early, aggressive treatment with these drugs. For some, these drugs can stop disease progression and halt joint damage.1

**Corticosteroids (Steroids)**
Corticosteroids, or glucocorticoids, often called “steroids,” are potent drugs that can reduce swelling and inflammation quickly. Most patients notice an improvement in symptoms within days of treatment. These drugs are closely related to cortisol, a hormone produced on the cortex of the adrenal glands. They are prescribed in widely varying doses, depending on the condition and goal of treatment. It has been determined that the potential for serious side effects increases at high doses or with long-term use. Doctors can
It is important to remember to be proactive if a person is experiencing RA symptoms. Early consultation with an orthopedic surgeon or rheumatologist is always recommended. Although there is no cure for rheumatoid arthritis, several medications are available including nonsteroidal anti-inflammatory drugs, steroids and biological therapies to help manage the disease.

About the Author
Debbie Uchida, CST, graduated from surgical technology school in May 1991, and currently works as a surgical first assistant at Saint Thomas Hospital in Nashville, Tennessee. She has a Synthes wrist fusion plate in her left wrist due to her rheumatoid arthritis. Ms. Uchida has served on the Tennessee State Assembly Board of Directors, as well as the education committee, and was awarded the Surgical Technologist of the Year recognition in September 2006, by her co-workers. She would like to respectfully dedicate this article to David Schmidt, MD, and Douglas Weikert, MD.

prescribe short-term, high-dose intravenous steroids in some situations, or give shots or local injections into specific joints for relief.

How they work
Corticosteroids are used to control inflammation of the joints and organs in diseases such as rheumatoid arthritis, lupus, polymyalgia rheumatica and vasculitis. In addition to their anti-inflammatory action, corticosteroids also are immunosuppressive. As a result, they may make certain individuals more susceptible to infection. Corticosteroids closely resemble cortisol, a hormone naturally produced by the body’s adrenal glands. This group of medications is available in oral, rectal and intravenous (IV) forms. When people take corticosteroids, their adrenal glands stop producing or slow down the production of normal cortisol. In general, corticosteroids are recommended only for short-term use in order to achieve remission. As valuable as they are in acute situations, corticosteroids are not effective in preventing flare-ups. They are usually given in the lowest possible dosage for the shortest amount of time. Frequent short-duration use, however, is not recommended.

Analgesics (Pain Killers)
Analgesics are pain-relieving drugs. Controlling pain is a vital part of treating arthritis. However, unlike NSAIDs, analgesics do not relieve inflammation. Acetaminophen is the most commonly used analgesic. Narcotic analgesic drugs can also be prescribed for more severe pain.

Biologic Response Modifiers (Biologics)
Biologic Response Modifiers (BRMs) stimulate or restore the ability of the immune system to fight disease or infection. BRMs are drugs derived from living sources, as opposed to being synthesized chemicals. Biological therapy is also called biotherapy or immunotherapy. The body normally produces these substances in small amounts in response to infection and disease. Using modern laboratory techniques, scientists can produce BRMs in large amounts for use in the treatment of cancer and other diseases, such as RA and Crohn’s disease.

How they work
Etanercept, infliximab, and adalimumab target TNF-alpha, one of the most important cytokines involved in RA. BRMs, which bind to TNF-alpha, render it inactive, interfering with inflammatory activity and ultimately decreasing joint damage. Anakinra, also a BRM, is considered an IL-1 antagonist. It is the first selective blocker of interleukin-1 (IL-1), a protein that is found in excess in rheumatoid arthritis patients. By blocking IL-1, Anakinra inhibits inflammation and pain associated with rheumatoid arthritis. It can be used alone, or in combination with DMARDs other than anti-TNF drugs. Abatacept is the first T-cell co-stimulation modulator approved for the treatment of RA. Rituximab, the world’s best-selling cancer drug, was FDA approved on March 1, 2006, to be used in combination with methotrexate to treat RA by reducing the signs and symptoms in adult patients, who have moderately-to-severely active RA and have failed with one or more anti-TNF drugs. It is the first treatment for RA that selectively targets the CD20-positive B-cells.

References
Wrist fusion or wrist replacement?

Another surgical option, which many choose over fusion, is wrist replacement. A total wrist replacement is generally indicated when a wrist has sustained a traumatic injury or has been affected by a severe degenerative disease, such as arthritis, and has not responded well to alternative treatments, such as a prescription drug regimen. A wrist replacement eliminates pain and recovers diminished strength in the wrist by restoring length to the muscles and tendons of the fingers and wrist, which improves motion and stability and improves the performance of many every-day activities. Total wrist arthroplasty has become increasingly popular with technological advancements constantly improving results. The most significant advantage to this procedure is that it allows postoperative joint movement, unlike a fusion.

The Procedure

Wrist replacement surgery can be performed under either general or regional anesthesia. Similar to an arthrodesis, an incision is made over the dorsum of the wrist. Sections of the distal ends of the radius and ulna are resected in order to make room for the artificial joint, which is composed of both metal and plastic components. Most of the first row of carpal bones is also removed.

After the wrist bones have been removed, reamers are used to prepare the central canals in the radius and metacarpals for the stems of the prosthesis, which comes in two parts. The radial component fits against the end of the radius, while the distal, or metacarpal component, replaces the extracted carpal bones in the wrist. Trial implants are used to determine the proper size of the implant. Once the correct size is established and the joint is securely fit into the wrist, a series of tests are performed to ensure proper range of motion and correct movement. The stems of the prosthesis are then permanently secured in place using bone cement. The tendons are returned to their proper position, and the skin is closed and secured with sutures. The wrist is bandaged and secured with a small splint to restrict movement while keeping the wrist in a natural position as it heals. A small drain may be placed in the wound immediately following surgery to prevent fluids from accumulating in the wound, which reduces the chance of swelling and the subsequent stiffness it can cause.

While the success rate for total wrist replacements is high, complications do occur, including infection, dislocation, imbalance and loosening. Although early joint replacements were fraught with these problems, complications have been greatly reduced. More attention is being given to the replacement wrist joint after many years of focus on knees and hips. This has generated newer and more effective joint designs and alleviated many of the problems with some of the earlier models. Most implants are expected to last between 10-15 years.

References

After living with RA for many years and surviving both a knee and wrist arthroscopy for complete synovectomies, my condition seemed to be in remission. However, in early 2006, new X-rays of my left wrist revealed a disturbing image. My wrist was in grave danger. My radius, ulna and all eight bones in my wrist were deteriorating and fusing together as one. The pain I experienced was indescribable. There were many days when I could not even feel my fingertips. I met with my orthopedic hand surgeon, Douglas Weikert, MD, to review operative and non-operative options. He warned me that avoiding surgery could potentially destroy my wrist, and the already intense pain would only worsen. Weikert advised that a wrist replacement would be very involved and would require more than one procedure to have a successful outcome. He told me that at my age, and with my occupation, this would not be his recommendation. Instead, he suggested a wrist fusion. This operation would eliminate my pain and rebuild my wrist. My only limitation would be not being able to bend my wrist.

Nervously, I sat trying to gather my thoughts. It was a huge decision, one that I would have to carefully weigh. However, continued pain, swelling and weakness quickly influenced my decision. I would not undergo the wrist replacement, but rather move forward and have the wrist fusion. I received my wrist-saving surgery in December 2006. I went into the operating room with the mindset that I would soon be healed.

I was slightly nervous on the morning of my surgery, but I remember feeling comforted with my teammates at my side. The major surgery lasted only two short hours. Dr Weikert spoke to my husband while I was in the recovery room, and he was extremely pleased with the fusion. There were no unexpected complications. After the operation, I was fitted with a sugar tong splint and I was back at home seven hours after my operation.

The pain was surprisingly tolerable. A few days of rest allowed me to get back on my feet. The splint was removed five weeks after surgery, and a short arm cast was applied. I began physical therapy (pt) immediately, and for those of you who haven’t had the pleasure of pt, it is not a pleasant experience! Intensive daily therapy is necessary to rehab the muscles and tendons. It is a vigorous and painful process, however, regaining my motion was crucial. Dedication, determination and a strong will guided me through my therapy. Every day I regained more motion in my fingers, and I was able to grip and hold items tightly.

I returned to my role as a surgical technologist 10 weeks after my wrist fusion was performed. I was once again setting up sterile fields, lifting heavy pans and assisting on all surgeries.

I am now almost two years post-op, and it is amazing how much stronger my wrist has become. A small, four-inch scar is all that is visible. Being a surgical technologist and first assistant helped me through both the surgery and recovery process. The knowledge I have gained regarding wrist fusions is a tremendous aid, and I am so very grateful and proud of my profession.

I would like to extend my deepest gratitude to the physicians at Tennessee Orthopedic Alliance for their on-going care and for helping me manage my rheumatoid arthritis. I would also like to thank Joanna Hearington for retrieving my medical information and Chris Bristow with Synthes Orthopedics.
Challenging and Changing the Experience of Pain:

Acute Pain Management in the Perioperative Setting in Patients with a Substance Abuse History

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Postoperative pain management presents a challenge in all surgical patients, particularly patients with a history of substance abuse. The current perioperative pain management protocol for recovering substance abuse patients, specifically those with a history of opioid addiction, is inadequate. Most patients undergoing a surgical procedure are treated with the same pain management assessment tools and medications with little regard for current addictions or recovering substance abuse patients.

Learning Objectives

- Identify the differences for administering pain control to patients who suffer from addiction versus those who do not.
- Define the physical and emotional components of pain.
- Describe the etiology of addiction.
- Evaluate the factors used to assess a patient’s pain level.
- Assess the benefits of MMT.
Prevention of withdrawal or relapse is mostly ignored; however, simple and manageable changes made in hospital policy, patient and staff education and patient assessment can improve this practice. Medication protocol can be individualized. All of these changes in practice can greatly enhance the care needed by this special population of patients by individualizing care rather than treating this population with no regard for their preexisting disease. Whether the patient is an active substance abuser or in recovery and working on a 12-step program, the patient’s emotional, physical and psychological reaction to pain is much different than a patient that has not suffered from addiction. Because of this abnormal reaction, the treatment chosen to control pain should be altered in order to meet the needs of this special population.

This issue greatly impacts practice as a surgical team member. The attitude of, “once a drug addict, always a drug addict,” needs to be altered. All patients, regardless of history, need equal treatment in regards to pain management in accordance with the Patient’s Bill of Rights in the United States. Just as a patient with a disease process, such as diabetes, has special needs, the substance abuse patient’s plan of care for postoperative pain management should be augmented accordingly.

Opioid-addicted patients, in particular, pose a great challenge in the postoperative setting. Since pain is such a broad topic with multiple facets, the research for this topic is limited to the patient suffering from past or present opioid addiction. The majority of the medications used in practice for postoperative pain management are opioid-based. Fear of triggering a craving in the recovering patient, or not managing the required serum drug levels to prevent withdrawal symptoms in the active patient while managing postoperative pain, is of constant concern.

Pain, as defined by Webster’s Medical Dictionary, is an unpleasant sensation that can range from mild, localized discomfort to agony. The word is derived from the Latin word poena, meaning a fine or a penalty. Pain has both physical and emotional components. The physical part of pain results from nerve stimulation and may be contained in a localized area, such as in an injury, or it can be more diffuse. The emotional components of pain range from anger and sadness to severe depression.

In today’s clinical practice, however, the most widely accepted definition of pain is the definition set forth by Margo McCaffery in 1968, which states that, “pain is whatever the experiencing person says it is, existing whenever they say it does.” Acute pain in the postoperative setting is present in a surgical patient because of a pre-existing disease, the surgical procedure, or a combination of the two. The inadequate treatment of acute postoperative pain has been recognized as a significant cause in the delay of hospital discharge and prolonged recovery time in surgical patients. Postoperative pain also increases morbidity and delays returning to normal living. Additionally, unrelieved pain causes a rise
in the body’s sympathetic response that leads to a rise in the heart rate and increases oxygen consumption and overall cardiac workload.\textsuperscript{13}

In today’s operating rooms and post-anesthesia care units, there is a severely undertreated patient population in reference to postoperative pain management. This population includes the individuals with an active addictive disease or a history of addictive diseases.\textsuperscript{14} A social stigma exists that addiction is a choice, however, addiction is a disease.\textsuperscript{15} A disease is defined as having an etiology, signs, symptoms and causes a specific illness to the body.\textsuperscript{16} Addiction is a chronic, relapsing and treatable disease that is characterized by a lack of control over consumption and compulsive use despite harmful consequences.\textsuperscript{4} Addiction also causes chronic mental illnesses and chemical changes in the patient’s brain.

Addiction’s etiology originates in a section of the midbrain called the mesolimbic dopamine pathway. When stimulated by drugs of abuse, such as opioids, this center releases the brain’s own endogenous endorphins. These endorphins are linked to the profound, euphoric feeling associated with drug intoxication. This feeling is so reinforcing that patients will seek to repeat using the drug despite dire consequences to their health and social life.\textsuperscript{7, 15} Thus, it can be deduced that addiction’s etiology is the stimulation of the dopamine pathway by drugs of abuse, and its signs and symptoms are the destructive behaviors that addicts often exhibit.

Perioperative pain management for the patient with an opioid addiction history must begin with a thorough preoperative assessment of the patient. Proper preoperative assessment is the first and most important step in proper postoperative pain management.\textsuperscript{9} Many pain assessment tools are available to clinicians, including numeric scales, visual analog scales and picture scales. Regardless of which assessment tool is utilized, the assessment must be done at regular intervals, and it must be well-documented to be effective.

The pain scales used in most settings help to provide accurate pain level assessment. However, all of these scales are very difficult to use in the acute postoperative phase of patient care due to the patient’s altered level of consciousness caused by the anesthetic medications used intraoperatively.\textsuperscript{13} In addition to the multitude of assessment scales used to assess a patient’s pain level, other factors should also be considered. A patient’s preoperative analgesic use (or substance abuse), pain management history, preoperative patient education and site of operation are a few of these considerations.\textsuperscript{17} All of these factors play an important role in the way pain is perceived and also how pain is communicated by the patient.\textsuperscript{3, 13, 17}

In most perioperative practice settings, a patient’s pain level is assessed preoperatively by a registered nurse with a numeric scale that ranges from 0 to 10. Although having a standardized pain scale is a positive attribute for obtaining continuity of care, it seems that the particular scale in use may not be completely effective. A more objective approach in the acute postoperative phase may be appropriate until the sedative effects of the anesthesia medications decrease.\textsuperscript{13, 17}

Use of the numerical scale is neither appropriate nor adequate for the acute postoperative setting. Clinical observations of the patient’s appearance, such as sweating, sighing and the inability to move may indicate a patient in pain. Other clinical objective observations, such as an elevated blood pressure, elevated heart rate and a lack of the ability to take a deep breath may also indicate pain in the postoperative patient.\textsuperscript{13, 17} In this regard, continuing education is needed in the perioperative setting. Proper training on clinical objective observations is required to adequately assess the sympathetic responses to pain.
that patients experience in the acute postoperative setting.\textsuperscript{11, 13, 17}

The assessment of pain in the acute postoperative phase of patient care is further complicated when the patient has a history of opioid addiction. This issue may, in part, be due to the preconceptions about the addictive behavior in this group of patients by caregivers and the reluctance of these patients to reveal their discomfort for fear of being judged and discriminated against.\textsuperscript{4, 7, 18} Patients with an addictive disease and pain have the right to be treated with dignity, respect and the same quality of pain assessment and management as all other patients. Thus, all patients who are admitted into the post-anesthesia unit must have their pain assessed and treated with the same resilience. Health care professionals are ethically bound to manage pain and provide care to all patients, including those patients known to have an active addiction or a history of an addictive disorder.\textsuperscript{4, 19} With the standard of practice at many facilities utilizing the numeric pain assessment tool, the addicted patient is treated no differently than a patient without a history of an addictive disease. Therefore, the pain management is inadequate, being directly related to the assessment tool in use.

Another consideration in evaluating this numeric assessment tool is that the treatment is subjective, since an elevated pain score may be viewed by the practitioner as drug-seeking behavior rather than actual pain. Furthermore, the patient may be reluctant to admit he is in pain and give a lower pain score than is appropriate for fear of being judged by the practitioner. The patient may also have exaggerated beliefs that even a small amount of opioids introduced into his system may cause a relapse.\textsuperscript{7} With these findings, it seems that the assessment of postoperative pain needs to encompass not only the physical aspect, but also the emotional and psychological aspect. It should be based on objective findings rather than the subjective assessment tools currently in use.

One change that will help to ensure adequate postoperative pain management for the patient with a history of opioid addiction is to obtain a history of substance abuse in the preoperative assessment. A full history and physical, including the patient’s drug history, recovery history and participation in a 12-step program, such as Alcoholics Anonymous or Narcotics Anonymous, should be obtained.\textsuperscript{5} Currently, many
facilities do not include questions on the preoperative assessment form relating to drug abuse history. After a detailed drug and recovery history is obtained, it can be determined whether or not the patient would like to consult a pain management specialist or an addictionologist. These specialists would follow the patient throughout the perioperative experience. The patient should be informed of the many nonopioid analgesic techniques that are available to them. The patient should also be reassured that these methods will be used fully before opioids are considered. For a patient who is recovering from an opioid addiction, the relief of knowing that they are being well taken care of and that they are not being judged will reduce the amount of tension and anxiety they have. This method has been shown to be an effective pain-management tool solely by itself. Many alternative pain treatment modalities are currently available, including epidural blocks, local and regional anesthesia, NSAIDs and local pain pumps. These methods constitute a multi-modal approach to analgesia. This approach is proven to be the best practice by many studies.

If the patient is actively abusing opioids or alcohol, the preoperative assessment will play a different role in the postoperative management of pain. Every patient who is opioid dependent is not necessarily obtaining the medication illegally. A population of patients exists who depend on opioids to simply perform activities of daily living because of debilitating pain from injury or illness. A patient who takes a large dose of opioid medication on a daily basis, prescribed or illegally, naturally has a higher tolerance for the drug. What seems to be an exuberant or exceedingly large amount of medication to the practitioner may be the normal amount for the patient or the patient’s tolerance level. Therefore, this amount would be ineffective for treating additional pain that is experienced during the perioperative setting. The opioid-tolerant patient will quickly enter withdrawal with a sudden decrease in the amount of opioids in his system due to not receiving the necessary doses. By maintaining the normal serum opioid level for the patient during and after the procedure, the practitioner can avoid this event. By addressing this issue, anxiety and tension, which potentially could complicate perioperative pain management and delay the patient’s surgical recovery, can be avoided. Withdrawal, if not properly medically managed, can be life threatening. Both situations can be avoided if a complete substance-abuse history is obtained and the plan of care is altered preoperatively.

Planning for postoperative pain management in the substance abuse patient is vital in his or her postoperative experience. Not all patients should be treated the same, regardless of their history of substance abuse. Additional preoperative or postoperative teaching must be done for this specific patient population. It is shown that patients who are well-educated on their upcoming experience complain of less pain postoperatively than patients who are unaware of the experience they are about to encounter. A generic preoperative education form is normally given to all patients in most facilities with orders that may include, “nothing by mouth for eight hours before surgery, discontinue aspirin two weeks before surgery, do not wear makeup or jewelry to surgery, and shower with antibacterial soap the evening before surgery.” The same is true for the postoperative education form, which may include orders such as, “take medication as prescribed, report any incident of fever above 101°F, do not remove dressings until your doctor sees you in the office, and keep extremity elevated if applicable.” Neither of these educational forms do much for the patient with a substance abuse history to relieve his or her anxiety.

It seems that the assessment of postoperative pain needs to encompass not only the physical aspect, but also the emotional and psychological aspect.
about pain or alternate methods he or she can use for postoperative pain management.

Since higher levels of preoperative fear and anxiety have been shown to have a direct exacerbation effect on postoperative pain,\(^5\) it is important to take adequate measures to decrease the patient’s preoperative fears with proper patient education and, if necessary, pharmaceutical and other alternative methods. The recovering addiction patient should be assured that his or her history of drug abuse will not be an obstacle regarding adequate and efficient treatment of postoperative surgical pain.\(^5\) Several medications can be given before surgery to help reduce postoperative pain.

Preoperative NSAID therapy has been shown to reduce postoperative inflammation and decrease pain and opioid requirements.\(^12\) NSAIDs work by blocking the action of cyclooxygenase, thereby inhibiting the production of prostaglan-

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### The use of methadone to treat opioid addiction

Methadone is a rigorously well-tested medication that is safe and efficacious for the treatment of narcotic withdrawal and dependence. For more than 30 years, this synthetic narcotic has been used to treat opioid addiction.

Illegal narcotics, such as heroin, as well as opiate-based prescription pain medications, release an excess of dopamine in the body and cause users to need an opiate continuously occupying the opioid receptor in the brain, forming a physical dependence, or addiction. Methadone occupies this receptor and is the stabilizing factor that permits addicts on methadone to change their behavior and to discontinue heroin use.

Taken orally once a day, methadone suppresses narcotic withdrawal for between 24 and 36 hours. Because methadone is effective in eliminating withdrawal symptoms, it is used in detoxifying opiate addicts. It is, however, only effective in cases of addiction to heroin, morphine, and other opioid drugs, and it is not an effective treatment for other drugs of abuse.

Methadone reduces the cravings associated with heroin use and blocks the high from heroin, but it does not provide the euphoric rush. Consequently, methadone patients do not experience the extreme highs and lows that result from the waxing and waning of heroin in blood levels. Ultimately, the patient remains physically dependent on the opioid, but is freed from the uncontrolled, compulsive and disruptive behavior seen in heroin addicts.

Withdrawal from methadone is much slower than that from heroin. As a result, it is possible to maintain an addict on methadone without harsh side effects. Many patients require continuous treatment, sometimes over a period of years.

Methadone maintenance treatment (MMT) provides the heroin addict with individualized health care and medically-prescribed methadone to relieve withdrawal symptoms, reduces the opiate craving and brings about a biochemical balance in the body. Important elements in heroin treatment include comprehensive social and rehabilitation services.

**Availability of treatment**

As of 1999, about 20 percent of the estimated 810,000 heroin addicts in the United States receive MMT. At present, the operating practices of clinics and hospitals are bound by federal regulations that restrict the use and availability of methadone. These regulations are explicitly stated in detailed protocols established by the U.S. Food and Drug Administration (FDA). Additionally, most states have laws that control and closely monitor the distribution of this medication.

In July 1999, the US Department of Health and Human Services released a Notice of Proposed Rulemaking (NPRM) for the use of methadone. For the first time in more than 30 years, the NPRM proposes that this medication take its rightful place as a clinical tool in the treatment of the heroin addict. Instead of its use being mandated by regulations, programs will establish quality assurance guidelines and have to be accredited. The proposed new system will allow greater flexibility by the treating physician and ensure appropriate clinical management of the patient’s needs. This proposed change in policy would eliminate most of the current regulations and allow greater clinical discretion for treatment by the physician. Accreditation establishes a clinical standard of care for the treatment of medical conditions. In the foreseeable future, clinic and hospital programs would be accredited by a national and/or state accrediting body. Responsibility for preventing the diversion of methadone to illicit use will remain with the Drug Enforcement Administration.
Is it safe?
Like any controlled substance, there is a risk of abuse. When used as prescribed and under a physician’s care, research and clinical studies suggest that long-term MMT is medically safe. When methadone is taken under medical supervision, long-term maintenance causes no adverse effects to the heart, lungs, liver, kidneys, bones, blood, brain or other vital body organs. Methadone produces no serious side effects, although some patients experience minor symptoms such as constipation, water retention, drowsiness, skin rash, excessive sweating and changes in libido. Once methadone dosage is adjusted and stabilized or tolerance increases, these symptoms usually subside.

Methadone is a legal medication produced by licensed and approved pharmaceutical companies using quality control standards. Under a physician’s supervision, it is administered orally on a daily basis with strict program conditions and guidelines. Methadone does not impair cognitive functions. It has no adverse effects on mental capability, intelligence, or employability. It is not sedating or intoxicating, nor does it interfere with ordinary activities such as driving a car or operating machinery. Patients are able to feel pain and experience emotional reactions. Most importantly, methadone relieves the craving associated with opiate addiction. For methadone patients, typical street doses of heroin are ineffective at producing euphoria, making the use of heroin less desirable.

Benefits
Evidence shows that continuous MMT is associated with several other benefits.

- MMT costs about $13 per day and is considered a cost-effective alternative to incarceration.
- MMT has a benefit-cost ratio of 4:1, meaning $4 in economic benefit accrues for every $1 spent on MMT.
- MMT has a significant effect on the spread of HIV/AIDS infection, hepatitis B and C, tuberculosis and sexually transmitted diseases. Heroin users are known to share needles and participate in at-risk sexual activity and prostitution, which are significant factors in the spread of many diseases. Research suggests that MMT significantly decreases the rate of HIV infection for those patients participating in MMT programs.

MMT allows patients to be free of heroin addiction. The National Institute on Drug Abuse found that, among outpatients receiving MMT, weekly heroin use decreased by 69 percent. This decrease in use allows for the individual’s health and productivity to improve. Patients were no longer required to live a life of crime to support their habit, and criminal activity decreased by 52 percent among these patients. Full-time employment increased by 24 percent. In a 1994 study of drug treatment in California, researchers found that rates of illegal drug use, criminal activity and hospitalization were lower for MMT patients than for addicts in any other type of drug treatment program.

The Drug Abuse Treatment Outcome Study (DATOS) conducted an outpatient methadone treatment evaluation examining the long-term effects of MMT. The pretreatment problems consisted of weekly heroin use, no full-time employment and illegal activity. Results of the 1-year follow-up showed a decrease in the number of weekly heroin users and a reduction in illegal activity after OMT. There was no significant change in unemployment rates.

Taken from the Executive Office of the President: Office of National Drug Control Policy. Available at: http://www.whitehousedrugpolicy.gov/publications/factsht/methadone/index.html
nonpharmaceutical methods include techniques such as imagery, meditation and breathing exercises. Some patients may wish to use these methods rather than using medications preoperatively. In addition, a patient may wish to have his or her Alcoholics Anonymous or Narcotics Anonymous-appointed sponsor present throughout the operative experience. Others may also wish to hold 12-step meetings before and after the procedure to assist in their mental and spiritual well-being. To relieve a patient’s anxiety, all efforts should be made when possible to abide by his or her wishes.

In the author’s current practice, the preoperative standing orders for all patients are to administer Versed, Robinul and Reglan. Versed is a benzodiazepam that reduces anxiety and causes mild sedation. While this medication is useful to reduce anxiety immediately preoperatively and is not contraindicated in opioid-addicted patients, it does very little to address the previously-stated issues that the recovering addict patient faces. Robinul is an anticholinergic medication that has no effect on the patient’s mental or emotional state. Reglan is an antiemetic and gastrointestinal stimulant that causes gastric emptying to help prevent nausea. These two medications do nothing to address the addicted patient’s concerns. Improvement in perioperative practice is necessary in relation to preoperative education and medication orders for this specific population of patients to address their needs.

In patients with no history of substance abuse, opioids are the first line medications used for postoperative pain management in most facilities. In patients with a history of substance abuse, it is important to make use of a multimodal analgesic approach. As previously mentioned, local anesthetics, regional and epidural blocks, NSAIDs, prostaglandin inhibitors and local postoperative pain pumps are many of the resources available to practitioners. Local anesthetics, regional and epidural blocks help to break the initial pain response felt by patients. Some medications, such as 0.25 percent – 0.75 percent Bupivicaine, last as long as three hours. Studies have supported the theory that opioid consumption can be brought to a minimum and maybe even eliminated from use with the proper advent of local anesthetics. In the case of epidural usage, the epidural catheter can be left intact until several hours after the procedure to ensure comfort for the patient in the acute postoperative phase.

Evaluation of the effects of the pain management therapy, whether it is a nonpharmacological or pharmacological method, should be performed at regular intervals. It is much easier to control pain if it is stopped before it begins rather than try to “play catch up.” Once the sympathetic response to the pain stimulus is initiated, it is harder to control and eventually halts the effects of the stimulus. Hence, the objective pain assessment methods, as discussed earlier and suggested by The World Federation of Society of Anesthesiologists, should be implemented.
ABOUT THE AUTHORS

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References

From concept to creation: A look at the drug discovery, development and approval processes

Teri Junge, CST, CFA, BS, FAST

Drug Discovery

The development of a new drug may be necessitated by an intentional quest for the treatment of a very specific need, such as the ongoing search for a drug that will treat tuberculosis more efficiently. The discovery of a drug can also be totally unintentional. On occasion, the intentional quest for a specific drug can result in findings that are totally unrelated. For example, the drug now known as sildenafil citrate (Viagra®) was originally developed with the hope that it would treat hypertension. When that effort was found to be unsuccessful, the drug was evaluated for its effectiveness in treating angina, at which time an unexpected side effect was noted. Sildenafil citrate is now a popular drug for treatment of erectile dysfunction.
DEVELOPMENT
A drug can remain in development for as long as 12-15 years, and the cost for each drug in development is more than 800 million dollars. In addition to the time and expense, the drug must also meet rigid guidelines set forth by the US Food and Drug Administration (FDA) before clinical trials can begin.  

PRECLINICAL TESTING
The preclinical testing of a drug under development may involve research that includes hundreds or thousands of existing compounds or new chemical entities. A new chemical entity (also known as new molecular entity) is a drug that contains active molecules that have never been included in any other new drug application. Each possible chemical or combination of chemicals is purified and systematically tested in the laboratory setting (including short term and long term animal trials) to determine if the chemicals produce the desired effect(s). This is called the pharmacology portion of the study. During this phase, the chemicals are also tested for purity and efficiency while being evaluated for pharmacodynamics. Pharmacodynamics is the interaction of the drug molecules with the target cells. The action of the drug substance causes an alteration in physiological activity but is incapable of initiating a new function. Three principal concepts affect drug interaction:  
1. Onset—the length of time from administration of the drug until action becomes obvious.  
2. Peak effect—The length of time that the drug is most effective.  
3. Duration of action—The length of time from administration of the drug until the action is no longer obvious.  

The frequency of future doses of the drug is determined by applying these three concepts along with consideration of other patient factors, such as their current condition, any comorbid conditions (other diseases occurring at the same time), the type of drug, route of administration and dosage.  

Results of the pharmacology studies are carefully recorded and any chemical that shows promise is advanced to the next step of preclinical testing. The others are abandoned, however, they may be used in development of future drugs.  

Next, toxicology studies are conducted to determine the dosage and safety of the potential drug for human use. Toxicology studies are performed on animals and are useful in determining the proper starting dosage for human studies. Any short and long term toxic, side, or adverse effects are noted. The effects may be mild (eg, skin rash, irritation at the administration site, etc) to severe (eg, hair loss, cancer, reproductive harm, death, etc). Also noted during the toxicology studies are any antagonists (reversal agents) to the drug and if the drug has the potential to be addictive. Several more chemicals may be eliminated during the toxicology studies.  

Pharmacokinetic studies, which encompass the entire process of the drug within the body, while not required, may also be performed during preclinical testing. The process of pharmacokinesis involves absorption, distribution, biotransformation and excretion. Pharmacokinetic studies provide information concerning the best route of administration (absorption), how the drug is transported to the target cells (distri-
A drug can remain in development for as long as 12–15 years, and the cost for each drug in development is more than 800 million dollars.

A drug can remain in development for as long as 12–15 years, and the cost for each drug in development is more than 800 million dollars.

DISTRIBUTION, how it is metabolized (biotransformation) and how the byproducts are eliminated from the body (excretion). This information may be very valuable in that it could save time and expense during the human trials by allowing for better predictions concerning the route of administration, size of the dose and timing of future doses.6

Only a few of the thousands of possible compounds or new chemical entities that are tested during the pharmacology and toxicology testing will be selected for clinical testing. Toward the end of the preclinical testing phase, the developers seek patent protection and submit an investigational new drug application (IND) to the FDA for those chemicals that show promise.3 The IND must be approved prior to the start of clinical testing of the drug.

CLINICAL TESTING (TRIALS)
Clinical testing on humans cannot begin until all of the pharmacology and toxicology testing is complete and the FDA has approved the IND. Once those requirements are met, the human trial must be designed, protocols established and safeguards put into effect in order for the value of the new drug to be compared to the current standard treatment for the same problem.

TRIAL DESIGNS
Several methods are available to researchers when designing a trial. The most common method, and the one considered to be the “gold standard,” is the randomized control trial (RCT). The word randomized means that the subject or subjects are chosen or placed in groups completely by chance. The word control means that one group of subjects does not receive treatment (or receives a placebo) so that the result of doing nothing can be compared to doing something. And of course the word trial is exactly that—an attempt. When participating in a RCT, the subjects, and sometimes even the administrators of the trial, do not know which group they have been placed in to eliminate biases in reporting the findings. The term “single blind” is applied when the subjects participating in the trial do not know if they are in the treatment group or the control group. The term “double blind” is applied when both the administrators and the subjects are unaware of the grouping status. Stratification, which is described as separation of the subjects into subgroups based on individual differences such as risk factors or severity of the disease/treatment under study, may also be applied.7

PROTOCOLS
A protocol is a written plan of action that follows the scientific process. Each trial will have several elements or protocols that must be established to clarify the goals of the trial and to ensure that the results of the trial are valid. There are also

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
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<tbody>
<tr>
<td>1.</td>
<td>Preclinical testing (pharmacology, toxicology, and pharmacokinetic testing—includes short and long term animal studies)</td>
</tr>
<tr>
<td>2.</td>
<td>An Investigational New Drug Application (IND) is submitted to the FDA and must be approved before human trials can begin</td>
</tr>
<tr>
<td>3.</td>
<td>A patent is obtained typically at the same time as the IND is submitted</td>
</tr>
<tr>
<td>4.</td>
<td>Clinical trials begin on humans (Phases 1, 2, and 3)</td>
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<tr>
<td>5.</td>
<td>Treatment use of an investigational new drug may be granted in urgent situations</td>
</tr>
<tr>
<td>6.</td>
<td>New Drug Application (NDA) is filed, reviewed, and approved</td>
</tr>
<tr>
<td>7.</td>
<td>Labeling of the new drug is approved</td>
</tr>
<tr>
<td>8.</td>
<td>Trademark is obtained</td>
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<tr>
<td>9.</td>
<td>Facilities that will manufacture the drug are inspected by the FDA</td>
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<tr>
<td>10.</td>
<td>Drug is manufactured, marketed, and sold (Phase 4 trials may be implemented)</td>
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clauses in the protocol that address withdrawal of a subject from the trial or stopping the trial altogether. The following list is a summary of the main protocol elements set forth by the FDA:

- General background information about the trial is provided including the statement of purpose.
- Specific objectives are listed.
- The design of the trial is specified.
- The number of subjects is identified.
- Eligibility rules are established.
- Subject selection criteria along with the rationale are set forth.
- The treatment plan (schedule) and duration of the trial is outlined and the subject is informed of the known benefits as well as any known or potential risks, including toxic, side or adverse effects of the trial drug.
- Methods for assessment of efficacy (including follow up visits, number of visits and necessary diagnostic studies) and safety are described.
- Data collection, storage, access and publication methods are defined.
- Any ethical, quality control, or quality assurance concerns are disclosed.
- The endpoint of the trial and rules for withdrawal from the trial are announced.
- Sources and methods of funding the trial and related expenses are made known.

All those involved with the trial, including the subjects, are given a copy of the protocol as part of the process of providing informed consent.

**SAFEGUARDS**

Numerous safeguards are in place to protect the subjects participating in a trial from human rights abuses that have been noted in the past. Some of the safeguards are listed below:

- The Health Insurance Portability and Accountability Act (HIPAA) of 1996 Privacy Rule—The privacy rule protects health information of the subjects of a trial. The subject may be asked to sign a release that would allow certain individuals (e.g., doctors, nurses, researchers) or groups (e.g., insurance providers including Medicaid and Medicare) related to the trial to share protected information about the subject, such as vital statistics including the subject’s name, contact information, social security number, medical diagnosis, treatment, results of diagnostic studies, etc. However, if the results of the clinical trial were to be published, the subject’s personal information would be withheld from the document. The full HIPAA privacy rule, as it applies to participation in clinical trials and other research efforts, is available online at [http://privacyruleandresearch.nih.gov](http://privacyruleandresearch.nih.gov).

- Informed Consent—The subject will be asked to sign a consent form. Informed consent means that the subject has been provided with information that is typically contained in the protocols that have been established.
to accompany the planned study, including the subject’s diagnosis, the risks and benefits of the proposed treatment, alternative treatments and of abstaining from treatment. The subject should have the opportunity to ask any questions that may arise.10

- Establishment of Institutional Review Boards—An institutional review board of at least five members, who meet certain requirements, is established to oversee most clinical trials. The board reviews all protocols, consent forms, advertising, etc. related to the trial and decides whether the materials are approved, need modification or are declined and if the trial can proceed. Once underway, the institutional review board meets to review the progress of the trial at least once a year—more often if necessary. Responsibilities of the review board include minimizing risks to the participants, ensuring that the risk to benefit ratio is appropriate, that selection of the subjects is carried out fairly, that the data produced from the trial is monitored, protecting confidential information, and regulating other safeguards that may be deemed necessary. The institutional review board may discontinue a trial earlier than planned due to unforeseen risks or severe toxic, side or adverse effects.8

- Audits—An audit of the clinical trial may occur at any phase. Audits are typically conducted by the institutional review board, but may also be accomplished by an outside entity such as the National Institutes of Health.8

HUMAN TRIALS

Human trials are conducted in the clinical setting in four phases. Each phase has a specific purpose with the overarching goal to achieve the desired therapeutic effect. Keep in mind that any of the safeguards can be activated during any phase, causing the trial to be delayed, suspended (put on hold) or terminated for a variety of reasons. Each of the four phases is described below:

1. Phase 1—The first phase of a trial is the first human contact with the drug and is conducted on a small group of people (20-80) who qualify. The subjects for phase one trials may be healthy or have the problem that the manufacturers of the proposed drug hope to treat. The protocols for phase one of the human trials are based on the knowledge learned from the pre-clinical trials. The purposes of phase one of the trial include identification of the ideal dosage, determination of the best route of administration, observation of the therapeutic effects
on the body, and notation of any toxic, side or adverse effects. The ideal dosage is considered to be the highest dose with acceptable toxicity. The drug is given via several different routes of administration (eg, oral, intravenous (IV), intramuscular (IM), etc) to determine which is the most effective. The subject is observed or is instructed to note the positive and negative effects of the drug. It may be necessary for the subject to undergo various diagnostic tests during the trial to gain information about the efficacy of the drug. This phase typically lasts one to two years.

2. Phase 2—The second phase of the trial is the second human contact with the drug and is conducted on a larger group of people (several hundred) who qualify. The subjects for phase two trials are selected because they have the problem that the manufacturers of the proposed drug hope to treat. The protocols for phase two of the human trials are based on the knowledge learned from the preclinical trials as well as the results of phase one of the trial. The purposes of phase two of the trial include determining the effectiveness of the drug in subjects with the disease or condition that the drug is designed to treat. The study design for phase two trials is usually a double blind randomized control trial.

3. Phase 3—The third phase of the trial is the third human contact with the drug and is conducted on a much larger group of people (several hundred to several thousand) who qualify. The subjects for phase three trials are selected because they have the problem that the manufacturers of the proposed drug hope to treat. The protocols for phase three of the human trials are based on the knowledge learned from the preclinical trials as well as the results of phases one and two of the trial. The purposes of phase three of the trial include determining the effectiveness of the drug in a larger population and identification of any long term risks (toxic, side or adverse effects) associated with the drug. The study design for phase three trials is also a double blind randomized control trial. Drugs in phase three may be approved for treatment use as an investigational new drug.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Goal(s)</th>
<th>Estimated Time</th>
<th>Number of Subjects</th>
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</table>
| 1     | Identify the ideal dosage  
|       | Determine the route of administration  
|       | Observe the therapeutic effects on the human body  
|       | Note any toxic, side, or adverse effects | 1-2 Years | 20-80 |
| 2     | Determine effectiveness of the drug in subjects with the disease or condition that the drug is designed to treat  
|       | Identify short term risks associated with the drug | 1-3 Years | Several hundred |
| 3     | Determine effectiveness of the drug in subjects with the disease or condition that the drug is designed to treat  
|       | Identify long term risks associated with the drug | Several Years | Several hundred to several thousand |
| 4     | Further evaluation of effectiveness of the drug  
|       | Identify long term safety of the drug | Varies | Varies |
drug. Toward the end of phase three, the New Drug Application is filed with the FDA.

4. Phase 4—The final phase of the clinical trial is not a required element, but may be an extension of the third phase in order to evaluate the drug for a longer period of time for safety and effectiveness. Phase four occurs after the New Drug Application (standard use of the drug) has been approved and may be useful in determining alternate (off label) or extended usages of the drug.

**DRUG APPROVAL PROCESS**

The United States Food and Drug Administration (FDA) is responsible for the approval process of new drugs.

**INVESTIGATIONAL NEW DRUG APPLICATION**

Before clinical testing on humans can occur, an investigational new drug application (IND) is submitted to the FDA. The application calls for reports of all preclinical testing and protocols for the clinical phases of the study of the drug. Additionally, an institutional review board must be set up to oversee the investigational phases of the trial. The FDA retains considerable control over the drug and the trials during the investigational phases.

**TREATMENT USE OF AN INVESTIGATIONAL NEW DRUG**

Occasionally, treatment use of an investigational new drug may be approved during the third phase of clinical trials (before the drug is approved for normal use) if the drug shows promise in treating a specific disease or condition. Permission may be granted for the drug to be used for treatment in life-threatening cases (called compassionate exceptions) if other treatments are not available or effective.

**NEW DRUG APPLICATION**

A new drug application (NDA) is filed with the Center for Drug Evaluation and Research (CDER), which is a branch of the FDA, late in the third phase of the clinical trial. The NDA will contain all information known about the drug, including all test results (laboratory, animal and human), toxicology reports, all that is known about the pharmacodynamics and pharmacokinetics of the drug, and any negative side effects or adverse reactions. Review of the application by the CDER can take up to two years, however, in priority cases, the time can be shortened to approximately six months. Once the CDER review is complete, the information is presented via an advisory committee to the FDA for final approval. Following approval, the final steps involve inspection of the manufacturing site for the drug and the wording for the label of the drug. Upon approval of the label information, the drug is marketable.

**PATENT PROTECTION**

Patent protection is typically obtained from the US Patent and Trademark Office (USPTO) during the preclinical testing period. Utility patents are granted to protect the rights of the individual or group of individuals who discover a new use of an existing compound or a new chemical entity that may become a marketable drug. Specifically, the right conferred by the patent grant is, in the language of the statute and of the grant
itself, “the right to exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention. Once a patent is issued, the patentee must enforce the patent without aid of the USPTO.13

A patent is valid for 20 years from the original date of application.13 Because of the length of time that a drug is in development, it is important not to file for the patent too soon because the patent may expire shortly after the drug becomes marketable, providing the developer a small window in which to recover their development costs. A drug patent prevents another manufacturer from producing the drug in generic form for the length of the patent.

TRADEMARK
A request for a trademark is filed with the USPTO near the end of the third phase of the clinical trial once the proprietary name of the drug has been determined and approval of the drug is imminent. A trademark is a word, phrase, symbol or design, or a combination of words, phrases, symbols or designs, that identifies and distinguishes the source of the goods of one party from those of others.14

CONCLUSION
The processes that result in drug discovery, development, and approval are long and expensive. The main goal is to ensure safety of the drug. “Safe,” in this sense, means that the benefits of the drug appear to outweigh the risks.11 The final goal is achieved when the cost of the drug has been set, the drug is being manufactured, the marketing of the drug is in process, and sales have begun.

ABOUT THE AUTHOR
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References
Ethical and legal issues in the administration of clinical trials

Tom Borak

Before a new drug can be mass produced and distributed in the medical community, it must be thoroughly vetted. One of the most critical steps in the process is the clinical trial phase, during which the drug is administered to human patients to establish, among other things, the ideal dosage and the toxicity level of the drug. The clinical trial phase is not only filled with health implications, but legal implications as well. Over the years, several lawsuits have been filed against pharmaceutical companies, hospitals organizing the trials and even international organizations that are administering trials abroad.

Because of the unknown variables associated with clinical trials, there are many ethical questions involved in this phase. Consider the Hippocratic Oath, a traditional rite of passage for medical practitioners, which states, in part:

_I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel…._

If the drug testing is in the trial phase, specifically one that is examining toxicity levels, can it honestly be said that this code is being followed?

Ethics can swing both ways. Others who favor the adage that, “the good of the many outweigh the good of the few,” may argue that the masses will ultimately benefit from the misfortune of a few if the trial should go wrong.

Despite many safeguards that are instituted with the patients’ safety and dignity in mind, many clinical trials still come under fire in the legal arena for issues ranging from misrepresentation of risks in the consent form to human rights abuses. These legal threats pose a challenge to those who administer these trials because they must walk a very thin line between what is legal and what is necessary to complete a successful and medically-relevant trial.

According to CenterWatch, a clinical trials listing service in Boston, there were approximately 50,000 clinical trials underway throughout the world in 2005. Increasing at a rate of 8-10 percent per year, the number in 2008 is likely more than 65,000. According to Alan C. Milstein, JD, there hasn’t necessarily been a dramatic increase in clinical trial-related suits, only more publicity about them.
“When you have a negative outcome,” says J Mark Waxman, JD, “questions are always raised whether [patients] understood the potential for a negative outcome and whether people properly administered the processes of the trial.”

Waxman believes that the increasing number of clinical trials, coupled with the fact that outcomes are not always positive, is pushing up the number of suits.

The ethical line often comes into play when clinical trial subjects are exposed to a potentially harmful situation as a means by which to test a drug’s effectiveness. In 2001, for example, the Maryland Court of Appeals ruled that researchers at an affiliate of Johns Hopkins School of Medicine could be sued for exposing children to hazardous levels of lead paint during a research project aimed at determining the effectiveness of varying lead abatement procedures.

In another 2001 case, the families of 13 patients in a melanoma study sued the Oklahoma University School of Medicine at Tulsa, the university’s institutional review board and the company that supplied the drug used in a vaccine for fraud. The suit alleged that the defendants failed to follow federal human subject regulations, claiming therapeutic misconception and saying that the study’s principal investigator was convincing the test subjects that the procedure was therapy, as opposed to an experimental process. According to the attorney for the defense, all of the subjects were terminally ill. The doctor didn’t tell them the state of the vaccine trial was in the toxicity stage—to see if it made them sick, not if it worked.

According to professionals in many fields, one of the biggest hurdles in the process is the clarity of informed consent.

“I don’t think the consent forms are worth the paper they’re printed on,” says Milstein. “There’s a real disconnect between what the subjects understand to be going on and what the consent form says.”

This situation presents a severe conflict of interests, as laid out by pharmaceutical defense attorney, Jay Mayesh, “In our current legal climate, one must err on the side of being very conservative in warnings,” he says. “But on the other hand, the problem is that the FDA doesn’t want you to be overly negative about a drug because then you’re scaring away patients who need the drug, could benefit from the drug and shouldn’t be scared away.”

In short, the language in the consent form must be written both thoroughly and in language that people can understand—outlining the methods, risks and purpose of the trial—while still generating interest and willing volunteers.

The ongoing battle over informed consent and the overall patient protection in clinical safeguards is a double-edged sword. The increasing threat of potential legal action can also lead to a decline in the quality of the research. As more investigators and institutions grow less willing to subject themselves to the risk of lawsuits, the protective precautions they take may dilute the quality of the research.

The methodology behind clinical drug trials is still very murky. While regulations and processes are constantly being scrutinized for reform, it remains a difficult and ethically-challenging path to walk.

References:
3. Grimes vs Kennedy Krieger Institute, 782 A.2d 807 (Md Ct App)
4. Robertson vs McGee, No. 4:01CV60 (D Okla)
Most surgical wounds are the result of a planned procedure and involve precise incisions that cause minimal tissue damage and minimize the risk of infectious complications. However, skin wounds may also result from a wide variety of physical insults, trauma and idiopathic causes.

Rapid and effective wound healing is of paramount importance to the surgeon and to the patient. Failure of wound healing generally leads to potentially life-threatening complications, additional surgical procedures, increased length of hospital stay, increased cost, and long-term disability.

This article provides an overview of the wound healing process and seeks to educate the surgical technologist on how to assess, classify and care for patients with surgical wounds, using evidence-based practice.

**THE NORMAL HEALING PROCESS**

The healing process begins following a breach in skin integrity and is described as an orchestrated, systematic interdependent, but overlapping process that leads to eventual repair. Wounds heal by either primary or secondary intention. A full thickness surgical incision will be repaired by primary intention.

In primary intention, the wound edges are brought together and held in place by sutures, skin glue or adhesive strips. Within 24–48 hours, the epidermis will have covered the surface of the wound.
the wound, but the healing process will still be continuing underneath.

Healing by secondary intention occurs where there has been an extensive loss of tissue, which means that the wound edges may not be brought together and so the wound has to heal through the process of granulation and epithelialisation. This is a more “chronic” healing process and takes much longer. An example of a wound healing by this method would be the regeneration and repair of a pressure ulcer.

Surgical technologists will mainly be associated with surgical wounds, so this article will concentrate on the acute healing process.

The sequence of events involved in wound healing, whether it is by primary or secondary intention, can be divided into four main stages: hemostasis, inflammation, proliferation and maturation.

Table 1 shows the major phases of wound healing and the interrelated concomitant events, also including information of the cells used to orchestrate these processes.

**TABLE 1: THE PHASES OF WOUND HEALING**

<table>
<thead>
<tr>
<th>Phase of Healing</th>
<th>Days Post Injury</th>
<th>Cells involved in the Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemostasis</td>
<td>Immediate</td>
<td>Platelets</td>
</tr>
<tr>
<td>Inflammation</td>
<td>Days 1-7</td>
<td>Neutrophils</td>
</tr>
<tr>
<td>Proliferation</td>
<td>Day 3-20</td>
<td>Macrophages</td>
</tr>
<tr>
<td>Granulation</td>
<td>Day 3-20</td>
<td>Lymphocytes, Angiocytes, Neurocytes</td>
</tr>
<tr>
<td>Contraction</td>
<td></td>
<td>Fibroblasts, Keratinocytes</td>
</tr>
<tr>
<td>Maturation</td>
<td>Day 21-2 years</td>
<td>Fibrocytes</td>
</tr>
</tbody>
</table>

**HEMOSTASIS**

Any skin trauma, surgical or otherwise, that results in the penetration of the dermal layers within the skin, will result in bleeding.

Hemostasis is defined as “the cessation of bleeding following injury,” with the amount of bleeding being dependent on the site of wound, size of the blood vessels involved, state of the individual’s health and anticoagulation status. Under normal circumstances, this process occurs within 10 minutes of wound formation.

When injured, blood vessel surfaces attract platelets to the site of injury. Platelets adhere, aggregate and form a procoagulant surface, promoting both the generation of thrombin and fibrin. This promotes clot formation and subsequent platelet degranulation, which releases platelet-derived growth factor (PGDF), a substance that triggers the clotting cascade, which results in vasoconstriction of the affected blood vessels, reducing the blood flow. Hemostasis is also classified as the early inflammatory stage of wound healing.

**INFLAMMATION AND WOUND HEALING (1-7 DAYS)**

Inflammation is a highly complex cellular surveillance system that is essential for both wound healing and antimicrobial defence. It has long been considered that the inflammatory response during wound healing is instrumental to supplying growth factor and cytokine signals that orchestrate the cell and tissue movements necessary for repair. There are two essential elements to the inflammatory events, namely the vascular and cellular cascades. These occur in parallel and are significantly interlinked. (See figure 1.)

**VASCULAR EVENTS:**

This stage signifies some marked changes in the caliber of the blood vessels, through morphological changes of the vessel wall and also in the flow of the blood through the vessels, which becomes turbulent. This gives rise to the classic signs of inflammation as seen at the wound, which are described in Table 2.

It is important to note that these signs and symptoms of inflammation after wounding are the same as the inflammatory process associated with tissue infection. This needs to be ruled out for the purposes of patient safety.

**TABLE 2: SIGNS AND SYMPTOMS OF INFLAMMATION**

<table>
<thead>
<tr>
<th>Signs/Symptoms</th>
<th>Physiological Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubor</td>
<td>Results from vasodilatation, mediated by prostacyclin and prostaglandins</td>
</tr>
<tr>
<td>Calor around the wound bed</td>
<td>Results from increased vasodilatation and increased metabolic activity</td>
</tr>
<tr>
<td>Tumor (swelling) in an around the wound bed.</td>
<td>Vascular endothelial gaps enlarge allowing the progression of plasma protein and fluids into the interstitial spaces</td>
</tr>
<tr>
<td>Dolor (Pain)</td>
<td>Increased pressure from oedema in the tissues, prostaglandins which irritate the nerve endings and damage to nerve endings.</td>
</tr>
</tbody>
</table>
CELLULAR EVENTS:
The cellular components of the inflammatory response include the early emigration of the Polymorphonucleo-
cytes (PNMs) to the wound site. The process of chemotaxis also attracts several other white blood cells to the wound bed. These include monocytes, leucocytes, eosinophils and basophils. Neutrophil leucocytes may be regarded as the first line of defense against infection at the wound site as they are described as actively phagocytic. This phago-
cytic activity involves clearing the wound site of dead and devitalized tissue, and also to neutralize and destroy any toxic agents at the site of injury, restoring tissue homeo-

stasis. The process of phagocytosis also releases lactic acid, which is one of the stimulants for proliferation in the next sequence of wound-healing events. A recent study has also highlighted that lymphocytes secrete a selection of lymphokines, which may assist in enhancing the rate of wound closure.

Towards the end of the inflammatory phase, the eicosanoids, which are chemical mediators generated from the inflammatory process, stimulate the synthesis of collagen from fibro-

blasts and the “ground substance.” This ground substance contains water, electrolytes, glycoproteins and a spe-
cific class of compounds known as proteoglycans, which are vital for cell-
to-cell and tissue adhesions. In addition, macrophage-derived growth fac-
tors are now at optimal levels, which is required for the influx of fibroblasts, keratinocytes, and endothelial cells into the wound.

The inflammatory stage of wound healing is complex and metabolically demanding. Thus it is of importance to note that any patient who may also present with diabetes or anaemia may experience a delay in the healing process.

PROLIFERATION (3–20 DAYS)
Proliferation refers to the development of granulation tissue, which takes place over a 28-day period. It involves the migration of fibroblasts, which begin to produce glycosaminoglycans, proteogly-
cans and the ground substance for granulation tissue and collagen. This is known as the formation of the extra cellular matrix (ECM). Newly-formed capillaries infiltrate the wound site to nourish and support the development of this connective tissue, a process known as angiogenesis. Angiogenesis takes place in distinct steps involving growth factors, cells and the ECM. Unregulated or insufficient vessel growth will result in delayed healing.

Some of the fibroblasts differentiate into specialist myo-

fibroblasts, which are responsible for the process of con-

traction. Contraction is defined as the pulling of wound edges together as the myofibrils start to contract around the wound edge. The purpose of this process is to reduce the amount of tissue required to fill the wound bed.
**MATURATION/REMODELING (21 DAYS–2 YEARS)**

This is the final stage of healing and can range from 21 days to two years. During this phase, the wound undergoes re-epithelialization, whereby macrophages release epidermal growth factor (EGF), which is responsible for stimulating the growth proliferation and migration of epithelial cells across the wound, covering the granulation tissue.

As the epithelial cells meet in the middle of the wound, the migration stops and the initial cells reconstruct to form a basement membrane. This basement membrane is of great physiological importance as epithelial cells can be easily sheared off the surface during wound dressing changes or vigorous wound cleaning. Although, the production of collagen enhances the tensile strength of the new tissue, it should be noted that this new tissue is not as strong as the original.

The wound at this stage is covered in scar tissue, which, along with the granulation tissue, is remodelled and strengthened over the course of the following one to two years.

**MOIST WOUND HEALING**

The concept of a moist wound healing environment has been promoted since the early 1960s. The process was first demonstrated in both humans and animals, which observed that by keeping wounds moist, the rates of healing were much quicker than those left to dry out under tensile-based dressings. Moisture in a wound acts as a transport medium for essential growth factors during epithelialisation and also promotes autolytic debridement. Therefore, dry or dead tissue would inhibit wound healing. Moist wound healing has many other clinical benefits as shown in sidebar at right.

**CLASSIFICATION OF SURGICAL WOUNDS**

According to Devaney & Rowell, surgical wound classification is an important predictor of the risk of postoperative surgical site infections and their associated risks. A standardized wound classification system has been in place since 1964, whereby all surgical wounds are classified according to their levels of risk of contamination. Table 3 identifies these classifications and gives some general descriptions of wounds within each category, including examples of the procedures from which these wounds have evolved.

Recent research has found that the management of wounds resulting from excision and drainage of the condition pilonidal sinus, caused by in-growth of hair in between the buttocks is controversial. These wounds are classified as dirty/infected and are therefore at risk for post operative wound infection. A recent systematic review has proposed that no clear benefit is apparent from either closure or healing by primary intention as compared to open healing by secondary intention.

---

**TABLE 3: SURGICAL WOUND CLASSIFICATION**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Wound Description</th>
<th>Surgical Procedure Associated with Wound Type</th>
<th>Infection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Surgical incision wounds/nonpenetrating</td>
<td>Exploratory laparotomy</td>
<td>1–5%</td>
</tr>
<tr>
<td></td>
<td>Surgical wounds that do NOT involve the respiratory, alimentary or genital tract</td>
<td>Prosthetic joint replacement</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vascular surgery</td>
<td></td>
</tr>
<tr>
<td>Clean/</td>
<td>Surgical wound that involves surgery within the urinary, alimentary, respiratory</td>
<td>Trans urethral resection of prostate</td>
<td>8–11%</td>
</tr>
<tr>
<td>Contaminated</td>
<td>tract. No breaks in sterile technique throughout the procedure</td>
<td>Bowel resection with formation of colostomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bronchoscopy with biopsy</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>Procedures that have major breaks in sterile procedures including contents from</td>
<td>Bile spillage during cholecystectomy</td>
<td>15–20%</td>
</tr>
<tr>
<td></td>
<td>the gastrointestinal tract</td>
<td>Surgery for diverticular disease</td>
<td></td>
</tr>
<tr>
<td>Dirty/Infected</td>
<td>Infected viscera prior to surgery, secondary to the presence of abscess.</td>
<td>Surgery for perforated appendix/bowel and formation of colostomy</td>
<td>27–40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peritonitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insertion of grommets for Otitis media.</td>
<td></td>
</tr>
</tbody>
</table>
FACTORS AFFECTING WOUND HEALING

The majority of wounds will heal normally without delay or complications. However, the capacity of the wound to heal swiftly is determined by intrinsic and extrinsic factors that will vary considerably between individual patients.\textsuperscript{25, 26} Table 4 identifies factors that the surgical technologist will need to consider when assessing surgical wounds.

<table>
<thead>
<tr>
<th>Intrinsic Factors</th>
<th>Extrinsic Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Nutrition</td>
</tr>
<tr>
<td>Disease process including</td>
<td>Smoking</td>
</tr>
<tr>
<td>• Diabetes</td>
<td></td>
</tr>
<tr>
<td>• Peripheral Vascular Disease</td>
<td></td>
</tr>
<tr>
<td>• Jaundice</td>
<td></td>
</tr>
<tr>
<td>• Renal disease</td>
<td></td>
</tr>
<tr>
<td>Wound perfusion</td>
<td>Radiotherapy</td>
</tr>
<tr>
<td>Oxygen tension</td>
<td>Wound Infection</td>
</tr>
<tr>
<td>Abnormal scarring</td>
<td>Medication</td>
</tr>
<tr>
<td></td>
<td>Anti Inflammatory Drugs</td>
</tr>
<tr>
<td></td>
<td>Immunosuppressant therapy</td>
</tr>
</tbody>
</table>

Whilst all these factors are of considerable importance, the role of nutrition is deemed to be a critical component in the wound healing process.\textsuperscript{3} It is widely recognized that when patients are in a poor nutritional state, wound healing is impaired and more likely to be complicated by infection.\textsuperscript{27} To this end, this section of the review will highlight the nutrients involved in the wound healing process.

An individual’s nutritional intake consists of both macronutrients, which include carbohydrates, fats and proteins, and micronutrients, which include minerals and vitamins. All of these substances have been shown to play a vital role in the wound healing process.\textsuperscript{28} In addition, it is important to note that fluid status is an essential part of nutrition, as this maintains adequate perfusion to the wound site, which is critical for transportation of both oxygen and nutrients.\textsuperscript{29}

It is important to identify any patient who may be at risk of malnutrition by performing a nutritional assessment. Should the patient be found to be at risk for, or be suffering from malnutrition, it is important to devise a suitable nutrition care plan, which will optimize their nutritional intake, thus promoting wound healing.\textsuperscript{30}

Early postoperative feeding has been shown to improve wound healing, and commencement within 24 hours of surgery is associated with optimal clinical outcome.\textsuperscript{31} Indeed, early food intake, or enteral feeding, which utilises the gut, as opposed to parenteral feeding, which delivers feed intravenously, is also recommended to promote enhanced recovery of patients after surgery.\textsuperscript{32} Regular food should contain sufficient energy and nutrients for the vast majority of patients and should be tried prior to any thoughts of possible nutritional support.\textsuperscript{33}

Any patient who has failed to achieve their optimal nutritional status through oral feeding, and those who cannot or will not eat may be candidates for enteral tube feeding.\textsuperscript{35}

It is also important to note that individuals with infected wounds have an increased requirement for energy, protein and other nutrients, which is secondary to losses of wound exudate and tissue granulation and may therefore benefit from nutritional support.\textsuperscript{30}

To this end, it is imperative that both the patient’s wounds and nutritional status are assessed on a weekly basis in the hope that this may prevent the development of both wound infection and malnutrition.\textsuperscript{36}

WOUND ASSESSMENT AND DRESSINGS

There are currently many sophisticated dressings available, made from a variety of materials, which can be used alone or in conjunction with other forms of dressings.

There are also several attributes of an ideal surgical wound dressing that surgical technologists should take into consideration prior to using any dressing. These are described in sidebar below.

**Attributes of a Surgical Wound Dressing**\textsuperscript{37, 38}

- The ability of the dressing to maintain a moist environment
- Ability of the dressing to absorb and retain exudate without leakage
- Enable gaseous exchange
- Allow ongoing wound assessment
- Absorb wound odor
- Avoidance of wound trauma on removal
- Cost effective and covered by health insurance systems
- Lack of particulate contaminants from the wound dressing
- Promote effective scar formation
- Easy to use
- Require infrequent changing
The dressings used should be easy to apply, painless on removal, allow earlier discharge from the hospital and require fewer dressing changes. The care of wounds and dressings used in wounds healing by primary intention, for example surgical wounds, are generally straightforward. The contact layer of the dressing placed directly over the wound is the most important, as it is required to provide protection from external contamination and absorb exudate. Straightforward surgical wounds that are likely to heal quickly, without complications, require simple, low-cost adhesive film dressings that are transparent, stay in situ for several days, and allow observation.

Some acute surgical wounds may be much deeper, causing trauma to underlying tissues, which may result in prolonged bleeding. These types of wounds may benefit from an additional layer of gauze or absorbent pads that provide compression and are classed as secondary dressings. These secondary dressings must not be too absorbent, as they may cause the primary dressing to dry out too quickly and delay the healing process.

It is important to recognize that every patient is an individual and the surgical technologist should take into account the patient’s underlying condition, for example whether the patient has diabetes, or any other factors that might delay the wound healing process, prior to making the choice of dressing.

Table 5 identifies the factors that should be taken into account when deciding which dressing to use.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Role in Wound Healing</th>
<th>Nutrient</th>
<th>Role in Wound Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>• Synthesis of new tissue</td>
<td>Vitamin A</td>
<td>• Stimulates collagen synthesis via the inflammatory response</td>
</tr>
<tr>
<td>(Requirements should be calculated on an individual basis and monitored closely)</td>
<td>• Optimization of tensile strength</td>
<td></td>
<td>• Improves cell mediated immunity</td>
</tr>
<tr>
<td></td>
<td>• Collagen Synthesis</td>
<td></td>
<td>• Promotes granulation of tissue</td>
</tr>
<tr>
<td>Arginine</td>
<td>• Optimizes tensile strength of the wound</td>
<td></td>
<td>• Avoid supplementation as this could cause toxicity</td>
</tr>
<tr>
<td></td>
<td>• Enhances immunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Improves secretion of growth hormone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>• Source of energy</td>
<td>Vitamin E</td>
<td>• Antioxidant effect, which can prevent cellular membrane damage</td>
</tr>
<tr>
<td></td>
<td>• Required to prevent protein being used as a source of energy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fats</td>
<td>• Major source of energy supplying 9 kcal/g</td>
<td>Vitamin B</td>
<td>• Required for release of energy from carbohydrate metabolism</td>
</tr>
<tr>
<td></td>
<td>• If an individual is overweight, low fat foods may be better choices.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Aim for weight maintenance not weight loss as this will compromise wound healing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Evidence equivocal surrounding the use of omega 3 supplementation and wound healing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin C</td>
<td>• Vital for collagen synthesis and subsequent cross-linking</td>
<td>Vitamin K</td>
<td>• Coagulation</td>
</tr>
<tr>
<td></td>
<td>• Required for angiogenesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Optimizes tensile strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Increases the absorption of iron</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Boosts immunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Natural sources from fruit and vegetables are best</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydration</td>
<td>• Dehydrated skin is less elastic, more fragile and susceptible to breakdown</td>
<td></td>
<td>The physiological role in wound healing is apparent but unclear. More research is required to identify and quantify these roles.</td>
</tr>
<tr>
<td>Copper, Selenium, Manganese &amp; Chromium</td>
<td>• The physiological role in wound healing is apparent but unclear. More research is required to identify and quantify these roles.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Wound healing is a highly complex physiological phenomenon, with many factors. Age, nutritional status and general health all play a role in the healing process. By understanding the physiology of wound healing, surgical technologists will gain greater insight into the importance of how their skills can impact the body’s healing response.

### ABOUT THE AUTHOR
Alison Shepherd is currently a nurse tutor at the Florence Nightingale School of Nursing and Midwifery at Kings College University London, where she teaches both pre and post-registration nursing students and serves as the module leader for the pre-registration Nursing Public Health Module. As a registered nutritionist with the Nutrition Society of the United Kingdom, Ms Shepherd is a freelance nutrition writer with more than 40 publications to her credit.
Maslow’s Hierarchy of Needs is a valuable assessment tool that is used in many different professions, particularly those in the fields of education and health care. The ideas of needs are addressed in order, as the body resolves the most basic needs for survival before moving on to more complex needs.

Many educational programs in the health care field teach Maslow’s hierarchy in order to address the needs of patients and where they are in their life from a psychological perspective, simply because it helps identify and address the needs of those particular patients.

The idea of using a hierarchy pyramid helps us to lay out the stages of need, starting with the base of the pyramid, which looks at physiological needs. As we work our way up the pyramid, the needs start to become more complex, and include safety needs, social needs, esteem needs, and finally, at the very top, we have self-actualization. This article explores the theories of Abraham Maslow in detail, as well as addresses the controversies that have been questioned in his theory. This article will also evaluate the impact of these theories on human behavior and assess each of the components comprised within Maslow’s Hierarchy Pyramid.

Biographical Outline
Born on April 1, 1908, in Brooklyn, New York, Abraham Maslow was the first of seven children. The son of under-educated Jewish immigrants, Maslow didn’t have many friends as a young

Learning Objectives
- Identify the different levels of Maslow’s Hierarchy of Needs
- Compare and contrast the differences between being needs and deficit needs
- Explain the process of self-actualization
- Examine how Maslow’s Hierarchy of Needs impacts patient care
- Consider the challenges to Maslow’s theories and formulate a response
Maslow later transitioned this idea over to human behavior and was able to establish physiological needs over safety needs, safety needs over belongingness needs, belongingness needs over esteem needs, and esteem needs. The needs, in turn, form the first four components of the pyramid, and are addressed as deficit needs. Self-actualization, the fifth component, addresses the need of being, which defines one’s own place in the universe.

When an individual does not have enough of something, he or she has a deficit, ultimately creating what Maslow has termed “deficit needs.” When individuals eat and drink, for example, the need for water and food is met, so there is no longer a motivating factor to obtain water or food, and the deficit need has temporarily been satisfied. Deficit needs comprise or make up the four lower components of Maslow’s hierarchy pyramid.

On the other hand, Maslow also mentions the idea of “being needs.” Being needs have nothing to do with deficit needs. Being needs are internal, and are at the very top of Maslow’s hierarchy pyramid, which ties into self-actualization. An example here might be drawing one’s own conclusions of where and who he or she is spiritually. This internal concept is addressed as self-actualization.

The following sections of this article will address each level of Maslow’s Hierarchy of Needs in more detail in an effort to see how they apply to individuals, and how they can define who and where an individual is in his or her life.
PHYSIOLOGICAL NEEDS

With so many different capabilities, from the regulation of temperature and hormones to the processing of water, food and the elimination of waste, the living body is the most unique machine in the universe. Despite its relative fragility, the human body can live for many years. Every single detail is so integral, from how the body processes oxygen through millions and millions of tissue cells, to the thousands of miles of arteries that carry blood and nutrients to those tissues. With this being said, there is still the need to meet the very basic essentials of life: the body must take on oxygen, water and food. Before any further growth can take place, this very basic need has to be met. This is what Maslow addresses as a physiological need—the need for the body to work in unison to accomplish the task of basic survival.

Physiological needs are influenced generally through the cravings that we have. If a person is thirsty, he or she finds a drinking fountain. Similarly, if the individual is hungry, he or she will find food. If the body is being deprived of oxygen, it will surely react. If there is a vitamin deficiency, the body has subtle ways of fulfilling that need.

One example of how the body regulates itself on a physiological level is by homeostasis. Homeostasis simply means to regulate. A part of the human brain, called the hypothalamus, plays an important role in keeping the body regulated by controlling the body’s thermostat, which is controlled by the release of several hormones called gonadotropins.

If a female produces too much estrogen, the hypothalamus releases a hormone called luteinizing hormone that triggers ovulation, therefore acting like a shut-off switch for the amount of estrogen present. If the thyroid gland produces too much thyroxin, the hypothalamus produces a hormone to switch off the flow of the thyroxin. These are just a few examples of homeostasis at work, however, there are many circulatory hormones that are needed to maintain normal bodily functions.

Another prime example is the release of the “fight or flight” hormones that are secreted by the adrenal medulla of the adrenal glands. If there is a need for the body to defend itself, these hormones will surge into action to prepare the body for fight or flight. These hormones, although they play an important role, are kept in compliance by regulatory mechanisms within the brain.3

Throughout life, the idea of physiological needs remains consistent. The need to maintain adequate physiological balance will always be essential...

The basic principles of Maslow’s hierarchy have been observed in primates.
believed that once the physiological needs are met in sufficient detail, people move on to address these more complex needs. Safety and security make up the next platform of the pyramid.

**SAFETY NEEDS**

Much like physiological needs require maintenance throughout life, so does the need to feel secure. This need is more psychological. With that being said, safety needs may be different for each individual, depending on where he or she is in life. For a child, this need may manifest as the need for a safe family environment. There has to be security in the home, with warmth and love.4

Safety needs may be different for each individual, depending on where he or she is in life. For a child, this need may manifest as the need for a safe family environment. There has to be security in the home, with warmth and love.

for a safe family environment.4 There has to be security in the home, with warmth and love. When a family is dysfunctional, it makes it difficult for that child to move up to the next level of social needs because fear is often present.

For adults, this need may be economic in nature. If a person loses his or her job, for example, fear and anxiety will have an impact on that person's social life, and may cause him or her to regress.5 Additionally, adults are not immune to the need of safety. In some parts of the world, where there is chaos, people are stuck at this level of needing to feel safe. The goal of consistently meeting the need for safety is to have stability in one's life. It is the idea of being able to walk around the block at night without the worry of being mugged. It is the idea of feeling secure in the workplace. It is conclusive that fear hinders one's ability to move on to the more advanced platforms of Maslow's pyramid.

**BELONGING NEEDS**

Advancing up the hierarchy pyramid, the next level represents the need to belong on a social level. The social level generally becomes the priority only after the physiological and safety needs have been sufficiently met and maintained. A sense of belonging can be felt when an individual becomes more focused on the desire to build relationships with others. This includes the desire for a romantic partner, to have close friends, and maybe to get married and have children.1

Again, this need will change depending on where an individual is in his or her life. For a young child, approval-seeking behaviors may become more commonplace. The child may engage in activities to get his or her parents’ attention by exploring or asking lots of questions. In a sense, the child needs to feel an emotional or social connection with his or her parents. As the child evolves into a teenager, he or she will more than likely become more socially active in peer groups. Generally, whatever gets reinforced, supported, or accepted by these peer groups will often determine which type of group the adolescent will affiliate him or herself with. This idea can be noticed at any point throughout an individual's life. As youths mature into adulthood, they tend to affiliate with those individuals or groups who accept them.

A sense or a need to belong, at any stage, is influenced by several factors. Some of these influences, for example, are socio-economic influences: the education level of parents and family, the neighborhood in which the child grows up and the type of schools where they are educated, as well as the children who attend those schools. Whatever type of behavior is learned and accepted, based on these variables, is likely the behavior that will form a particular individual's character and self-esteem.

The level of belonging must be established because of its effect on one's self-esteem. If the level of belonging in the hierarchy model is low, or an individual is viewed negatively by peers in that group, he or she may develop social anxiety and may withdraw toward a level of people in which he or she fits in socially. If a child grows up in a neighborhood where there are street gangs, and attends schools in that neighborhood with the families of those street gangs, then the likelihood of the child to adapt and take on that form of character becomes more likely. According to Maslow, the reason for this behavioral pattern is likely due to the peer groups that the child grew up with.

This is not meant to imply that all children who grow up in this type of neighborhood will join a gang, simply that there is a higher likelihood of that outcome. On the other hand, if a child is brought up in a more affluent neighborhood, it is likely that the parents will also be more educated. In this scenario, it is more likely that the child will develop and adapt to the peer groups in which education is more of a priority. The influence in a child’s upbringing starts
with a home and family that secures the previous levels of Maslow’s hierarchy by meeting and maintaining the foundation levels of needs. Relieving any anxiety or fear will help put more emphasis on social development, and with this will come a healthier self-esteem.

**Esteem Needs**

Once the needs of physiology, safety and belonging have been met, the individual will now move on to the needs of their self-esteem. Self-esteem, like all the prior needs, must also be maintained. This is the highest platform in the category of deficit needs. The process of growth, when addressing one’s self-esteem, builds the bridge to one’s awareness. Self-esteem begins to establish itself in life as early as age two. Maslow’s hierarchy addresses two levels of self-esteem. One of those is a lower level and the other is a higher level.

The higher form of self-esteem that Maslow addresses is that of self-respect. This higher form of self-esteem requires less maintenance because through accomplishment, it becomes a permanent part of who the individual is. We can say that once a person has gained respect for himself or herself, it is much harder to lose that respect or to have it taken away. People on the higher end of self-esteem generally like who they are. The idea of confidence in ability, the mastery of something, or the competence that is established in what these people do, supports this higher form of self-esteem.

These forms of self-esteem should not be confused with an individual having high or low self-esteem. Individuals with low self-esteem often have a low opinion of themselves and their self-image. As a result, inferiority complexes are present in the individual. With this idea in mind, Maslow contends that the majority of people’s psychological problems are due to low self-esteem. The realization here is that if a person don’t like himself or herself, or who he or she is or what he or she has accomplished, then that person will be more critical of himself or herself. Through that process, negative self talk is born, and can create a barrier to achieving personal success.

How does low self-esteem impact these lower and higher forms of self-esteem in general? If an individual has low self-esteem, the lower form of self-esteem affects the individual on a social level. The individual may, for example, constantly attempt to seek or validate feedback and acceptance on a social level from his or her peers. With regard to the higher form of self-esteem, in the individual with low self-esteem may display a lack of respect for himself or herself and the expectations that they place upon themselves would be unrealistic, or perhaps in some cases these expectations would be placed by others rather than being placed by the individuals themselves.

It is amazing that all of the prior needs within Maslow’s hierarchy, including physiological, safety, and even belongingness needs are frequently met, especially in modern society and developed countries. Imagine if more people just had a little respect for themselves in the grand scheme of things.
SELF-ACTUALIZATION

Self-actualization is defined by Maslow as the single component of being within the hierarchy model. Being, in this sense, means not being a part of the deficit needs as they appear within the lower chain of the hierarchy. This need is independent—there must be some accomplishment of all the other deficit needs, which are best defined as what we appear to be, according to the standards of society. Self-actualization is the internal dialogue that everyone establishes at some point in their lives. In order to do that, there must be some establishment or satisfaction of the prior needs. Once all of the previous needs have been met, an individual can direct his or her focus toward a true calling. Usually when a person is hungry, or they don't feel safe, or they feel unloved, the focal point leans towards resolving those issues, therefore disrupting the focus on self-actualizing. With self-actualization, being able to pinpoint how one truly feels about something is often a little more challenging to figure out, or it can be the determining factor of how well he or she is connected with his or her self and abilities.

People who are self-actualizers are focused on what matters most in defining who they are. Once self-respect is gained, the individual can take a more proactive approach to bettering themselves, as well as being able to remain focused on resolving any dilemmas ...

Self-actualizers are focused on what matters most in defining who they are. Once self-respect is gained, the individual can take a more proactive approach to bettering themselves, as well as being able to remain focused on resolving any dilemmas ...
OVERVIEW

When looking at Maslow’s hierarchy pyramid, an important concept to remember is that anyone at anytime can regress back to any point within the hierarchy structure that Maslow addresses. How does this impact human behavior? Looking back at the very basics of physiological needs for example, people need to feel good. It does not matter if a person is employed as a janitor or a top-notch cardiac surgeon, if he or she is diagnosed with a disease that impacts them physically, he or she is likely to regress back towards satisfying any physiological needs that may come about. The affected individual’s attitude towards the prognosis of this disease will likely contribute towards a shift in his or her priorities. Emotionally, the feelings of love and belonging may be impacted in the sense that they may want to ensure that their loved ones are safe when they pass.

With regard to esteem, for some, there may be a great sense of loss, while others may come to terms with the fact. With that being said, there are circumstances that affect each individual with regard to where he or she stands in the hierarchy pyramid.

Is everyone a self-actualizer? Yes. For each individual, this experience is different. It is experienced at different depths depending on individual life experiences. The more in touch one is with one’s inner self, the better he or she can control, and often master, one’s self-talk. It is also important to remember that all individuals are constantly impacted by the forces of life, some of which are far beyond personal control. When the opportunity arises to experience this hierarchy, and the needs of deficit are fully met, it allows the individual to make a closer connection with the concept of self-actualization. Also, when these deficit needs are met, self-actualization, in a sense, is likely to become even more enhanced.

The bottom line is that everyone is effected emotionally at every level of Maslow’s Hierarchy of Needs. If early life experiences as a child are positive, and needs are being met, that individual will excel in the area of self-confidence and self-esteem at much faster rate. It helps to establish a strong foundation for life. Later, the individual is able to establish a much stronger set of coping mechanisms when one of the deficit needs isn’t being met. Additionally, when adverse circumstances confront the individual, he or she is often better-equipped with the ability to problem solve and confront the challenge confidently.

Conversely, if early life experiences as a child are negative, and needs are not met, that individual’s foundation isn’t as secure, and he or she is not as likely to excel in self-confidence and self-esteem, rather, he or she is likely to get trapped a state of constantly seeking approval from peers. He or she may develop a fear of making mistakes.

The majority falls somewhere in between what is positive in life and what is negative. Ultimately, individuals who develop a strong, well-established foundation are likely to be emotionally strong and can exercise a stronger sense of self control. Those whose foundation is shaky and not very stable will focus more on protecting it, therefore having less confidence in that foundation.

ABOUT THE AUTHOR

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A SURGICAL CURE FOR

Chronic Blushing:
Endoscopic Thoracic Sympathectomy

by Kara Showalter, CST

The sympathectomy procedure was developed in the mid-nineteenth century. It was well known at the time that the sympathetic nervous system affected many body systems, and it was surmised that the autonomic nervous system played a role in how the body regulates many body functions, including response to changes in environment, exercise and emotion.

HISTORY

William Alexander first performed the sympathectomy in 1889, while attempting to treat many conditions, including goiter, epilepsy, glaucoma and severe chest pain. Surgeons were unsuccessful in treating most of these conditions, although they did find a few situations where sympathectomy actually helped. For example, it helped stop intractable chest pain in those suffering from inoperable heart disease. It also put an end to uncontrollable sweating and blushing.7

A posterior approach to the procedure was developed in 1908, to provide better access to the nerve tissue in the chest cavity, but it required resection of the ribs, which was very painful. A supraclavicular approach was developed in 1935, to lessen the pain involved with the surgery, but this approach was more prone to damaging important nerves and blood vessels. Because of the risky nature of sympathectomy, the open approach was never a very popular procedure. It fell even further out of favor with the popularization of lobotomy.7

Sympathectomy did not become popular again until the 1980s, when an endoscopic version was pioneered by Goren

LEARNING OBJECTIVES

▲ Examine the historical development of ETS
▲ Explore the physiology of the sympathetic nervous system
▲ Evaluate the indications for a potential ETS candidate
▲ Compare and contrast symptoms of Reynaud’s Syndrome and erythromelalgia
▲ Analyze the ETS procedure, along with the reversal process
Claes and Christer Drott in Sweden. This endoscopic approach decreased recovery time and risks of nerve and vessel damage due to its minimally-invasive nature. Today, the procedure is commonly used to treat hyperhidrosis, facial blushing and some pain disorders affecting the sympathetic nerves.7

The sympathetic trunks are a paired bundle of nerve fibers that run from the base of the skull to the coccyx in a downward direction just lateral to the vertebral bodies. The sympathetic trunk is a vital part of the sympathetic division of the autonomic nervous system, as it allows nerve fibers to travel to spinal nerves that are superior and inferior to the one in which they originated. These nerve fibers are called sympathetic chain ganglia, and they are responsible for delivering information to the rest of the body regarding stress situations and the fight or flight response. These sympathetic ganglia are the structures that are destroyed during a sympathectomy.2

INDICATIONS
Endoscopic thoracic sympathectomy (ETS) is performed for a variety of reasons: it is a treatment for idiopathic craniofacial erythema (chronic blushing), hyperhidrosis, and some pain disorders resulting from an overactive sympathetic nervous system.7

Idiopathic craniofacial erythema is a medical condition characterized by severe, frequent and uncontrollable reddening of the face, which is often unprovoked. It is unknown why people are afflicted with this condition, but it is definitely the result of an overactive sympathetic nervous system. Chronic blushing is primarily diagnosed by reviewing the patient’s history and by ruling out other conditions that would cause reddening of the skin. Options for conservative treatment for chronic blushing include oral medications and behavioral therapy. Several types of medications are used as treatment for idiopathic craniofacial erythema. Anxiolytics, such as Valium®, are used for anxiety; beta-blockers, which blunt the body’s reaction to stress; or anticholinergic drugs, such as robinal, ditropan, or propanthelin.3

Cognitive behavioral therapy has proved to be the most effective noninvasive treatment for chronic blushing. Cognitive behavioral therapy is a type of psychotherapeutic approach based on the idea that our thoughts, not external stimuli, dictate our behaviors. The benefit of this method is that it teaches patients how to deal with dysfunctional emotions in a systematic, goal-oriented process.
Another indication for ETS surgery is hyperhidrosis, or excessive sweating of the palms, face, or axilla. This condition is characterized by abnormally increased perspiration in excess of that required for regulation of body temperature. Hyperhidrosis is a condition that is inherited as an autosomal dominant genetic trait. Since it is a congenital condition, diagnosis usually results from a family and patient history. Conservative treatments include anticholinergic medications, such as iontophoresis, oxybutynin and robilon. Aluminum chloride can be used topically in high concentrations as an antiperspirant and injections of botulinum toxin type A can be used to disable the sweat glands.

Raynaud’s Syndrome and complex regional pain syndrome are pain disorders that can be treated with ETS surgery. Raynaud’s Syndrome is a painful vascular disorder that affects blood flow to the extremities when exposed to cold temperatures. Raynaud’s is caused by a hypersensitivity of the sympathetic nervous system causing vasoconstriction of the peripheral blood vessels, leading to tissue hypoxia. Chronic, recurrent cases can lead to atrophy of the skin, ulcerations of the skin, and ischemic gangrene. Raynaud’s diagnosis is made by patient history and physical examination as well as by ruling out other conditions that could cause the vascular symptoms. Warming devices and vasodilators are the main forms of conservative treatment for Raynaud’s Syndrome.

**ALTERNATIVE TO ETS?**

**What is Cognitive-Behavioral Therapy?**

The term cognitive-behavioral therapy (CBT) does not represent a distinct therapeutic technique, rather, it serves as a general classification for a variety of therapies in the same family. According to the National Association of Cognitive-Behavioral Therapists, there are several approaches to cognitive-behavioral therapy, including: rational emotive behavior therapy, rational behavior therapy, rational living therapy, cognitive therapy and dialectic behavior therapy.\(^1\)

The foundation of CBT is based on the idea that an individual’s thoughts cause feelings, behaviors and reactions, not external stimuli, such as other people, situations or events.\(^1\) If this is in fact the case, then theoretically, people are capable of making themselves feel or act better, even if the situation has not changed, simply by changing the way he or she thinks about the given circumstance.

While other forms of therapy, such as psychoanalysis, can take years, CBT is a much faster process. This has to do, in part, with the differences in the therapist–patient relationship. A cognitive-behavioral therapist’s role is to uncover the client’s life goals and then figure out how to help the client reach these goals.\(^5\) As stated by the National Association of Cognitive-Behavioral Therapists, “the therapist’s role is to listen, teach and encourage, while the [patient]’s role is to express concerns, learn and implement that learning.”\(^6\) Put another way, cognitive-behavioral therapists do not tell their patients what their goals should be, or what they should tolerate. Instead, they direct their patients in ways to think and behave in order to obtain what they want.

The ultimate goal of cognitive-behavioral therapy in regard to chronic blushing is to help stop the reaction by teaching the patient to adjust his or her expectations of social norms. According to researchers, people who blush excessively tend to have unrealistic expectations of how they should behave in social situations. They fear that even a small mistake will be mocked by others, so they become unnecessarily anxious and start to blush. In comparison, babies and small children, who have yet to develop these feelings about social interactions, do not blush at all.\(^7\) By working with a cognitive-behavioral therapist, patients are able to work on changing the way they approach certain circumstances, reducing the likelihood of a flare up.

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Complex regional pain syndrome (CRPS) is a chronic progressive disease characterized by severe pain and swelling of a limb, accompanied by changes in the skin. Pain associated with CRPS is continuous and may be heightened by emotional stress. Moving or touching the affected limb is often intolerable and eventually the joints become stiff from disuse and the bones and muscles atrophy as well. The cause of CRPS is unknown, but is associated with an overactive sympathetic nervous system and diagnosis can be made by performing a series of tests. These tests include thermography, which is a technique used for measuring blood flow; radiography, which can detect osteoporosis up to two weeks after the onset of CRPS; and electrodiagnostic testing, which can differentiate between type I and type II CRPS. Conservative treatments for CRPS include physical and occupational therapy combined with pain and anti-inflammatory medications. The physical and occupational therapies are important components to managing CRPS primarily because they desensitize the affected body part and restore range of motion to improve the functionality of the limb.

Surgery is only recommended for severe and disabling cases of these conditions, and the procedure varies for treatment of each disorder. The sympathetic ganglia are identified by the level of the vertebra to which they correspond. For idiopathic craniofacial erythema and facial sweating, the nerve tissue is interrupted at the T2 level. In cases of hyperhidrosis of the palms, nerve tissue is interrupted at the T3 level. For hyperhidrosis of the axilla, the T3, T4, and T5 levels of nerve tissues are all interrupted. In treatment of both Raynaud’s syndrome and complex regional pain syndrome, the T2 through T4 nerve ganglia are destroyed. Other variations in the procedure depend on the method used for interrupting the nerve tissues. Most surgeons prefer to clamp the nerves instead of completely resecting them primarily because the clamping method leaves the possibility of easier reversal of the procedure.

**PROCEDURE**

Several types of equipment and instrumentation are essential to successfully perform ETS. Necessary endoscopic equipment includes video towers, a fiber-optic light source and endoscopic instrumentation. A 5mm telescopic endoscope and a camera cord and light cord are also very important for performing this procedure. Endoscopic graspers, endoscopic scissors and clip appliers are also required. Soft tissue instrumentation that must be available during ETS surgery includes a hemostat, Adson pick-ups with teeth, a needle holder and suture scissors. Anesthesia will require a double lumen endotrachial tube to deflate the lungs and allow exposure of the surgical site.

In order to prepare for the initial incision, the patient must be positioned, prepped, draped and anesthetized, and some practical considerations about room set-up must be made. The patient will be in the supine position with both arms extended on padded arm-boards and a safety strap will be applied two inches proximal to the knees. General anesthesia will be utilized for this procedure, with the use of a double lumen endotrachial tube. The prep will begin at mid-chest level and extend from the shoulder, including the axilla, to the iliac crest and down to the table on the affected side. Four folded towels will then be placed around the incision site and a fenestrated drape will be placed on top of the towels. An important consideration regarding room set-up is that ETS is a bilateral procedure. To allow the surgeon an unobstructed view from either side, a video tower should be placed on each side of the patient. An extra set of both prepping and draping supplies should also be opened to allow the transition from one side to the other.

To begin the procedure, the surgeon will direct the anesthesia provider to deflate the patient’s lung on the affected side to facilitate exposure of the thoracic cavity. A #11 blade will then be used to make a 5mm incision between the patient’s second and third ribs in the axillary plane. A disposable thoracic port is inserted through the incision and a 5mm telescopic endoscope is inserted through the port. The sympathetic chain is identified at the level that will be interrupted (between T2 and T5), and an endoscopic scissor is used to open the pleura. At this point, the nerve will be separated depending on the surgeon’s preference of method, either by resecting it with...
endoscopic scissors or by clamping it with an endoscopic clip applier. The port is then removed, and a small thoracic catheter is inserted through the incision, which is then closed. Once the incision is closed, the lung is re-expanded, eliminating all residual pneumothorax through the small thoracic catheter. The catheter is then removed and wound closure is completed. Steri-strips™ and Mastisol® are applied to the closed incision, and the patient’s other side is prepped and draped. The same procedure is then repeated on the opposite side. Re-intubation is not required during the transition since a double lumen endotrachial tube is used. A double lumen endotrachial tube allows the anesthetist to deflate and re-inflate either lung to facilitate exposure of the operative site. At the conclusion of the procedure, the patient will be transported to PACU, where a postoperative chest X-ray film will be taken to rule out residual air left in the thoracic cavity.

Patients usually stay in the hospital overnight after ETS surgery, and patients may resume normal activities in about one week. Most patients who undergo ETS have suffered for many years from socially-disabling conditions, so instant relief from these conditions dramatically increases their quality of life, providing a 90-95 percent satisfaction rate. Prognosis for patients suffering from Raynaud’s Syndrome, or complex regional pain syndrome, depend on how far the disease has progressed, making the satisfaction rate unpredictable.

Complications associated with ETS include infection, bleeding, respiratory problems, damage to nerves or arteries, compensatory sweating and Horner’s Syndrome (Oculosympathetic Palsy). Compensatory sweating is the most common side effect of ETS surgery, occurring in approximately 50 percent of patients. It is a condition called compensatory hyperhidrosis, in which sweating is shifted from the hands, armpits, face or scalp to the upper and lower back, lower chest, abdomen, buttocks, groin, and backs of the thighs. Compensatory hyperhidrosis is usually mild, and most patients are able to tolerate it without any problems. Rarely, compensatory hyperhidrosis can be very severe, even more so than their original hyperhidrosis. This can cause patients to express regret regarding their sympathectomy and wish to have a reversal.

Horner’s Syndrome is the most serious complication of ETS. It results in a slightly smaller pupil and a disfiguring asymmetry of the face due to a slightly drooping upper eye-lid. This complication is a caused by damage to the uppermost thoracic nerve-node, also called the ganglion stellatum, and can only be reversed by plastic surgery to resect the affected eyelid (blepharoplasty). The risk of this complication depends mainly on the surgeon’s familiarity with the procedure. Pneumothorax can also be a significant risk of this procedure. If any air is left in the thoracic cavity, respiratory problems may occur.
REVERSAL
Occasionally, patients wish to have thoracic sympathectomy reversed. Various reasons for dissatisfaction with the procedure include compensatory hyperhidrosis, obesity and the inability to perform exercise, and a lack of temperature control for the upper body. Resumption of nerve conduction and return to normal sympathetic regulation after a reversal of a thoracic sympathectomy can be a very lengthy process. Initial symptoms of recovery of sympathetic regulation may take six to nine months to show after a reversal. The reversal technique depends on the method used to interrupt the nerve tissues during the original operation.

If the surgeon who performed the original operation cut the nerve tissue in order to interrupt it, a nerve graft must be performed to restore the nerve. In this method, the location where the operation was previously performed is prepared by refreshing the edges where the nerve was previously cut. Then a nerve graft is harvested from the ankle region, usually the sural nerve is used, and is connected to the divided edges of the sympathetic chain with a biological gluing agent.

The cutting method is the hardest to reverse. The clamping technique is a much easier version of sympathectomy to reverse, which is why it has become the method of choice for ETS surgeons. In reversal of the clamping method, the clip is simply removed from the nerve and the nerve is allowed to regenerate on its own. This method has shown much quicker improvement in compensatory sweating, and the healing process can be reduced to about three to four months. Both reversal methods are performed endoscopically.6

CONCLUSION
Although it should only be used as a last resort method of treatment due to the possibility of complications, endoscopic thoracic sympathectomy has proven to be an effective treatment for various conditions, including chronic blushing, hyperhidrosis, and pain syndromes associated with an overactive sympathetic nervous system.

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Valium is a registered trademark of Roche Pharmaceuticals.
Steri-strips is a trademark of 3M Corporation.
Mastiol is a registered trademark of Ferndale IP, Inc.
**Man-on–Fire Syndrome**

by Tom Borak

Imagine waking up one morning and feeling like your entire body, from head to toe, was on fire. You can’t move from your bed, the skin on your toes is cracked and bleeding from the swelling in your feet. There is nothing you can do to dull the sensation of being engulfed in flames.

For a handful of people around the world, this nightmare is a daily reality. They suffer from a rare disease called erythromelalgia (EM), also known as Man-on–Fire Syndrome.

According to the U.S. National Library of Medicine’s medical subject headings, a “rare” disease is classified as, “a large group of diseases, which are characterized by a low prevalence in the population. They frequently are associated with problems in diagnosis and treatment.”¹ According to a story by ESPN’s Steve Cyphers, which follows the journey of Kate Conklin, an EM patient who is training for a triathlon, the disease affects fewer than 400 people in the United States.²

The name, erythromelalgia, is derived from three Greek words: erythros (red), melos (extremeties) and algos (pain).³ First described in the 1870s, there is still relatively little that is known about this disease, which, due to its rarity, is often misdiagnosed or attributed to a psychological disorder. The symptoms are most common and most severe in the feet and hands. Flare-ups usually occur due to exposure to warmth, and physical activity is often a catalyst. A flare-up will often begin with an itching sensation, which builds into the severe pain and burning symptoms. The pain can be so intense that patients cannot walk.³ Erythromelalgia is not related to complex regional pain syndrome (CRPS), although it can mimic some of the symptoms.⁴

One troubling aspect of the disease is that most cases are idiopathic, and can manifest at any point in life. Conklin, for example, did not experience symptoms until she was 28-years old.² Conversely, remissions are possible, but infrequent.⁴ Since there is no known cause, there is no known cure. EM can also be a secondary development to additional medical conditions, including autoimmune, neurologic or blood disorders. Infrequently, EM can develop following an injury or surgical procedure.⁵ Some people have the inherited or primary form of EM, and usually have other family members with the disease. Recently, an EM gene was identified, as were several mutations to this gene. Apparently, each affected family carries a different mutation, further complicating the process of finding a cure.⁴

There is evidence that suggests that erythromelalgia shares a common pathophysiology with Raynaud’s Syndrome. In some instances, a patient has exhibited both conditions – sometimes simultaneously. Despite this possible relation, there is no evidence to suggest that the ETS procedure can have a positive impact on EM patients.⁵

An erythromelalgia flare-up is indicated on both shins.

Due to the nature of the illness, EM patients cannot wear close-toed shoes or socks. This can be particularly challenging during the winter months, when frostbite is a legitimate concern. Because many patients cannot feel pain unless it is more acute than the constant pain of EM, they are unaware of the damage that is occurring in other parts of their bodies. Many patients instinctively soak the affected parts of their body in cold water as a means to reduce the swelling and the burning sensation. However, according to the The Erythromelalgia Association, it has been demonstrated that icing or soaking can actually result in increased flaring, thus making the symptoms worse. Other problems may include skin tissue and nerve damage, infections, even severe ulcers that can take months to heal. Contrary to outdated medical information, this method of treatment is not advisable.⁴ In one extreme case, a patient suffered near-fatal hypothermia related to the constant cooling to control the symptoms.³

Research is ongoing to learn more about the causes of erythromelalgia, and to search for a cure. For more information on Kate Conklin, go to ESPN.com and type “Outside the Lines: Burning Desire” into the search bar.

**Resources:**

In-Office Facial Plastic Surgery:

Autologous Fat Grafting

by Nydia Morales, CST

Plastic surgery for pure cosmetic enhancement is becoming more commonplace. As the practice spreads, procedures have become more affordable, and opened the door for middle-income individuals to receive treatments that were previously reserved for the wealthy. In the process, these procedures have also become more refined.

What is it that compels people to pursue an elective surgery, such as plastic surgery? In order to answer this, one can reference Maslow’s Hierarchy of Needs. Maslow’s pyramid breaks down into five distinct categories: physiological needs, which are basic biological needs, including food, water and warmth; safety needs, which are environmental needs, including safe and secure surroundings; love and belonging needs, including the basic social requirements of friends and intimate relationships; prestige and esteem needs, including respect, which give people a sense of accomplishment and self-worth; and self-actualization, which is the point at which one finally recognizes and accepts his or her ultimate potential. *Please see Editor’s Note.

Self-dissatisfaction is a confrontation with one’s self. It can also influence the way a person perceives that he or she is viewed by others. When a person is insecure about physical aspects of his or her body, prestige and esteem needs are negatively affected. These perceived short-comings can have a negative effect on a person’s evaluation of self-worth. In some instances, surgery offers a legitimate remedy. The ultimate goal of a cosmetic surgi-

Learning Objectives

▲ Evaluate the success of autologous fat grafting
▲ Compare and contrast the methods of facial augmentation
▲ Review the preparation and procedure for autologous fat grafting
▲ Examine the history of plastic surgery
▲ Gauge the wide-spread use of plastic surgery in the United States
Fat is a natural choice for grafting material. An early pioneer in the use of autologous fat grafting for facial remodeling in the 1970s, Tolbert Wilkinson, MD, found that the health and safety benefits of using the patient's own fat for the injection are significant. Since the donor is the patient, the immune system accepts the transplanted fat. The transplanted fat can also be removed, making the procedure reversible. The cells are fragile in the first month following the transfer, so the physician can crush and remove the graft if necessary. This option is utilized if the result of the procedure is too bulky. The lips are an example of where this result may occur.

In addition, Wilkinson was impressed by the durability of the grafts, noting that some of his patients' grafts were still working after 15 to 20 years. Fat, or adipose tissue, is a naturally-occurring substance in the human body. Fat storage results from the conversion of nutrients from dietary fats, proteins and carbohydrates acting together to create a stockpile of reserve energy. Fatty acids and glycerol are broken down in the stomach and small intestine before the lymphatic system transforms them into triglycerides, which are then stored as adipose tissue. Sugars from carbohydrates, such as glucose, are also converted into fatty acids and stored.

Fat is typically stored on the abdomen, hips and thighs. Since it lays dormant on the body, it is an accessible entry point for easy collection. This fat is used for grafting. Some of the most common facial locations that are treated with fat grafting include the nasolabial folds, marionette grooves, lips, chin, jaw line, neck and cheeks. Patients receiving procedures in these areas are often seeking a rejuvenating effect. There are many factors that can cause the dermis and epidermis to atrophy, creating indentations in the skin. One of the more common causes is the after-effects of cortisone injections that were used to treat cystic acne lesions. Other causes include aging, sun exposure and smoking. Fat grafting provides the augmentation needed to fill these areas.

Proportionate distribution of the grafted fat is the key to maintaining the balance of the face. The surgeon will begin by filling in the cheeks and lower eyelids before moving on to other parts of the face. The purpose is to give the fat a chance to settle and take its placement on the face. In the neck area, subcutaneous fat is injected to fill in the creases.

When a person is insecure about physical aspects of his or her body, prestige and esteem needs are negatively affected. These perceived short-comings can have a negative effect on a person's evaluation of self-worth.

There are many options with plastic surgery. Procedures can range from buttocks and breast augmentation to rhinoplasty or a facelift. The central focus of this article is autologous fat grafting, a technique that can be utilized in a variety of procedures. The method is minimally traumatic, and the fat is harvested from the patient's own abdomen or thigh. It is then injected into the area that is in need of enhancement or remodeling. For facial procedures, the most common areas include cheeks, nasolabial folds, the tip of the nose, chin and lips. The ultimate goal of the procedure is to create a natural appearance.

While autologous fat grafting has proven to be highly successful, it is not the only option for facial augmentation. Other methods include injectable fillers, such as hyaluronic acid, collagen-based structural fillers and calcium-based microspheres, suspended in a water-based gel. These artificial fillers are used to conceal deep wrinkles, nasolabial folds, the nasojugal groove and provide enhancement for the lips. Chemical peels, including trichloroacetic acid, salicylic acid, alpha hydroxyl acid and phenol are used to resurface the skin. Finally, intradermal injections of botulinum toxin type A may be used to improve deep wrinkles, crow's feet and frown lines between the forehead and eye brows. It can also be used as a treatment to improve oily skin. All patients are strongly advised to consult their plastic surgeon regarding specific goals and needs.

The challenges vary from patient to patient. In some cases, it may take years before the patient is fully satisfied and is able to accept himself or herself. Personal appearance is affected by aging, trauma, disease and heredity. One of the most common phrases in a plastic surgeon's office is, “I don't like my...” Walking through the doors of a cosmetic surgery facility can be a hard step, but it is the first step in resolving the unhappiness that has manifested.

Fat grafting, a technique that can be utilized in a variety of procedures. The method is minimally traumatic, and the health and safety benefits of using the patient's own fat for the injection are significant. Since the donor is the patient, the immune system accepts the transplanted fat. The transplanted fat can also be removed, making the procedure reversible. The cells are fragile in the first month following the transfer, so the physician can crush and remove the graft if necessary. This option is utilized if the result of the procedure is too bulky. The lips are an example of where this result may occur.

In addition, Wilkinson was impressed by the durability of the grafts, noting that some of his patients' grafts were still working after 15 to 20 years. Fat, or adipose tissue, is a naturally-occurring substance in the human body. Fat storage results from the conversion of nutrients from dietary fats, proteins and carbohydrates acting together to create a stockpile of reserve energy. Fatty acids and glycerol are broken down in the stomach and small intestine before the lymphatic system transforms them into triglycerides, which are then stored as adipose tissue. Sugars from carbohydrates, such as glucose, are also converted into fatty acids and stored.

Fat is typically stored on the abdomen, hips and thighs. Since it lays dormant on the body, it is an accessible entry point for easy collection. This fat is used for grafting. Some of the most common facial locations that are treated with fat grafting include the nasolabial folds, marionette grooves, lips, chin, jaw line, neck and cheeks. Patients receiving procedures in these areas are often seeking a rejuvenating effect. There are many factors that can cause the dermis and epidermis to atrophy, creating indentations in the skin. One of the more common causes is the after-effects of cortisone injections that were used to treat cystic acne lesions. Other causes include aging, sun exposure and smoking. Fat grafting provides the augmentation needed to fill these areas.

Proportionate distribution of the grafted fat is the key to maintaining the balance of the face. The surgeon will begin by filling in the cheeks and lower eyelids before moving on to other parts of the face. The purpose is to give the fat a chance to settle and take its placement on the face. In the neck area, subcutaneous fat is injected to fill in the creases,
or the cartilage to provide a smooth appearance. If there is a depression from the eyebrow to the supratarsal fold, the surgeon injects the fat superficial to the orbicularis oculi muscle. In this way, autologous fat grafting can be used as an alternative option to an overall face-lift procedure, or as a supplement to the face lift.

How successful is the autologous fat grafting procedure? A first-of-its-kind study was recently documented on the longevity of the procedure’s results. In the 2009 survey, titled, “Autologous Fat Grafting: Long-term Evidence of Its Efficacy on Midfacial Rejuvenation,” 33 patients were injected with 10 ml of autologous fat to the midface region. Pre- and postoperative three-dimensional colorimetric analysis (photographs) was used to assess volume change. Magnetic resonance imaging (MRI) was also used to record volume retention. Of the 33 participants, only eight patients needed 3 ml of touch-ups (secondary procedures).

An additional aspect of the study used ultrasonography to record the results of the fat transfer. The patients were scheduled for quarterly follow-up visits for one year following the procedure. The results of the study revealed a high rate of successful fat retention: 51 percent at three months, and 45 percent at six, nine, and 12 months. The eight patients with touch-ups had a lower percentage (29.6) of volume retention.

Patients who have undergone abdominal surgery are not good candidates for autologous fat grafting due to the possibility of developing a ventral hernia.

PREOPERATIVE PROCEDURE

The surgeon reviews the procedure preoperatively, and also obtains and reviews the patient’s consent form and medical history. He or she then takes preoperative photographs of the patient, which will be used to illustrate the postoperative difference. The surgical technologist remains in the O.R. at all times, and the patient’s vital signs are constantly monitored. For this type of outpatient procedure, there is no circulating nurse or anesthesiologist present. Before the procedure begins, the surgical technologist confirms that the consent form has been signed and countersigns it, reviews the medical entry and takes and records vitals, including blood pressure and pulse oximeter readings. Close attention is given to any irregularities, such as cardiac dysrhythmia, or anything that could indicate a potential medical risk.

ANESTHESIA

The choice of anesthetic varies depending on numerous factors, including the patient’s overall health, current medications, consideration of the surgeon and patient preference, and the number and length of time of the procedures that are being performed. Based on these variables, a facial procedure can be performed under general anesthesia, an IV with sedation, or local anesthesia. Most cases are treated with a local anesthetic.

This patient did not like how her nasolabial folds (cheek wrinkles) made her look older and tired. She was also concerned that her skin wasn’t “smooth” and had lots of oil. Autologous fat injections were performed to help improve the deep wrinkles and a salicylic acid peel was done to effectively smoothen her skin and reduce the oil. Fillers would not have been as effective given her anatomy.
The local anesthetic of choice is a tumescent solution, consisting of 400 ml of normal saline, 90 ml of one percent lidocaine without epinephrine, 10 ml of 8.4 percent sodium bicarbonate and 1 ml of epinephrine (1:1000).

If the patient is nervous prior to the procedure, the surgeon may choose to administer 5-10 mg of diazepam, sublingual, to treat the anxiety. Post-operatively, acetaminophen is often sufficient to manage the pain. In some instances, however, a narcotic pain reliever is prescribed.

In addition, the patient will be prescribed a postoperative antibiotic to prevent bacterial infection. Three of the primary medications are azithromycin; cephalexin, which is used for patients who have certain heart problems in order to prevent coronary infection, such as bacterial endocarditis; and clindamycin, which is used for patients who have an allergic reaction to penicillin.

**INSTRUMENTATION AND SUPPLIES**

<table>
<thead>
<tr>
<th>Supplies for Fat Grafting Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small, medium and large blunt cannulas (3 mm)</td>
</tr>
<tr>
<td>10–15 syringes (10 ml)</td>
</tr>
<tr>
<td>30-gauge needles</td>
</tr>
<tr>
<td>4 x 4 Sterile gloves</td>
</tr>
<tr>
<td>Bouffant / cap</td>
</tr>
<tr>
<td>Wash basin</td>
</tr>
<tr>
<td>Long, cotton-tipped applicator</td>
</tr>
<tr>
<td>Drapes: suitable for operative sites</td>
</tr>
<tr>
<td>Suture and dressing – surgeon’s preference</td>
</tr>
<tr>
<td>Marking Pen</td>
</tr>
<tr>
<td>Electrosurgical pencil with needle-tip electrode (kept on the side, should it be needed)</td>
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</tbody>
</table>

**FAT GRAFT DONOR SITES**

The lower umbilical region is an easy-access donor site, and is widely used. Other donor sites include:

▲ Inner thigh: In the frog-leg position with the knee flexed and externally rotated (flat on table). The puncture is made on the skin fold along the inguinal line.

▲ Anterior thigh: With the patient in the supine position and both legs straight, a puncture is made along the inguinal line.

▲ Outer thigh and buttock: The patient is placed in the lateral decubitus position, and a puncture is made on the fold of the buttock.

▲ Waist roll: Also using the lateral decubitus position, a puncture is made on the inferirolateral extend of the fat pad.

▲ Hip: Similar to the waist, the patient is placed in the lateral decubitus position, but the puncture is made in the posterior of the fat pad.

▲ Triceps: The patient is placed in the lateral decubitus position, and a puncture is made at the postlateral extend of the axillary fold.9
Some of the most common facial locations that are treated with fat grafting include the nasolabial folds, marionette grooves, lips, chin, jaw line, neck and cheeks.

**OPERATIVE PROCEDURE**

The patient is seated in the reverse Trendelenburg position. The patient’s face, as well as the puncture area of the donor site, are cleansed with alcohol wipes. The face is also cleansed with surgi-scrub. Sterile drapes are placed on the thoracic and epigastrium region, as well as on the lower portion of the hypogastrium region.

Once the area has been prepped, the surgeon outlines the planned surgical paths with a sterile marking pen (on both the abdomen and face). He or she then administers the local anesthetic. When the anesthetic has taken effect, the first step in the procedure is to harvest the fat that will be transplanted in the graft. A 30-gauge needle is used to make the entry point for the blunt cannula that is attached to a syringe. In a thrusting, lateral-to-lateral movement, the fat is aspirated from the donor site, while the surgical technologist applies fingertip pressure to the site.

Once the physical harvesting of the fat is complete, the syringes are placed in a centrifuge (to be operated by the surgeon) to remove excess water and impurities. The process takes a few minutes, and at its completion, approximately ¾ of the contents of each syringe is useable fat. The fat ranges in color from hues of orange to yellow. The closer the color is to orange, the greater the actual fat content. The surgeon applies a 5-0 nylon suture to the donor site, while the surgical technologist applies an antibiotic ointment to a long, cotton-tipped applicator. The surgical technologist then applies the antibiotic ointment to the wound, which is covered with a 4x4 dressing, followed by a cold compress.

The surgeon then injects the fat graft in the specified areas that have been clearly marked. He or she makes approximately three subcutaneous tunnels in each graft site, injecting the fat as the needle is slowly withdrawn. The surgical technologist then cleanses the area and applies 4x4 dressings. A cold compress is applied in 20-second intervals, alternating sides on the affected region of the face, if the procedure is symmetrical. The chair is then raised to a seated position, and vitals are taken again and recorded. Prescriptions for antibiotics (mandatory) and prescription pain relievers (if needed), or over-the-counter extra strength acetaminophen are noted by the surgeon. Written postoperative instructions are given to the patient, and a follow-up appointment is scheduled for one week.

This patient did not like how her deep smile lines (nasolabial folds) made her face look older and tired. She wanted long lasting results and was not keen on using any artificial materials in her face. Therefore, autologous fat injections were easily done to provide her with a natural and refreshing look to her face. In addition, a slight and subtle elevation was accomplished to her cheek area resulting in a more youthful contour to her face.
POSTOPERATIVE CARE
The patient is instructed to maintain ice packs on the recipient area for 48-72 hours post surgery. For a facial procedure, the head must be elevated while sleeping to minimize edema. Sleeping with two pillows is generally sufficient. Strenuous exercise is not allowed, although short walks are acceptable. The patient is also placed on a diet that restricts salt intake in order to reduce facial swelling. In some cases, swelling in the recipient area can last up to six months.

POSTOPERATIVE COMPLICATIONS AND FOLLOW-UP
Postoperative complications for plastic surgery, including autologous fat grafting procedures, include infection, bleeding and hematoma. Bruising, swelling, and mild discomfort are also common, although not normally considered serious.

After the procedure, follow-up visits are scheduled for one week, two weeks, and one month. At that time, postoperative photos are taken. The surgeon retains extra vials of the patient’s fat, and refrigerates them should touch-ups be needed in the future.

*Editor’s Note: An in-depth look at Maslow’s Hierarchy of Needs is available in the August 2009 issue of The Surgical Technologist.

ABOUT THE AUTHOR
Nydia I Morales, CST, was an elementary school teacher before entering the medical field. She graduated from New York University Langone Medical Center’s surgical technology program in New York City, and passed the CST Certification exam in September 2007. She presently assists Kamran Jafri, MD, as his surgical technologist in facial plastic surgery.

REFERENCES

From the Author
The patients I have encountered are very representative of Maslow’s definition of prestige and self-esteem needs. What I have come to understand is that a personal dissatisfaction with a particular element of one’s body does not necessarily indicate a sense of vanity. Being unhappy affects the total body and mind, which can be concealed to a certain degree. The serious-minded patient usually takes a year before finally confronting themselves to actually start to change that personal perception. Once the process gets started, and especially after seeing the finished result, the happiness sets in. I have heard numerous patients acknowledge, “I should have done this a year ago!”

One of the best parts of my job occurs when the surgeon hands the mirror to the patient after a procedure. The expression of relief is evident, and the dissatisfaction that entered the office dissolves as the patient walks out the door. Being a part of helping a person boost his or her self-esteem is both fulfilling and gratifying.

This article is dedicated to my mom, Maria C Morales. Through life’s difficulties she gave me the strength to focus and finalize this writing. May she rest in peace. June 14, 2009.
The practice of plastic surgery is much older than one might expect. It is believed that nose reconstructions were performed in ancient India as early as 2,000 BCE, when amputation of the nose was an accepted form of punishment. Surgical procedures are noted in Sanskrit texts, including *Sushruta-samhita*, which was written in approximately 600 BCE. It describes the reconstruction of the mutilated nose, using tissue from the cheek. However, most of the modern procedures that are used today date back to the 1880s and 1890s.

Aesthetic, or cosmetic surgery became very popular in the 16th century, during the Renaissance. This resurgence in interest paralleled the syphilis epidemic of the time. Syphilis is a sexually-transmitted disease caused by the bacterium *Treponema pallidum*. Advanced cases of syphilis can cause disfigurement and even death. The primary role of aesthetic surgery at the time was to rebuild the noses of syphilitics, so they could become less visible in society.

It was during this time that Italian surgeon Gasparo Tagliacozzi and French surgeon Ambroise Paré began experimenting with the early Indian ideas, sparking a renewed interest in the use of local and distant tissue to reconstruct complex wounds, giving rise to the modern concept of plastic surgery.

Pierre Joseph Desault, a French anatomist and surgeon, coined the term “plastic surgery” in 1798. Derived from the Greek word *plastikos*, which means “fit for molding,” plastic surgery eventually became the dominant label for all featural and reconstructive surgery in the early 19th century. The catalyst that sparked the widespread use of the term was the 1818 publication of *Rhinoplastik*, a monograph on the reconstruction of the nose by Karl Ferdinand von Gräfe. A superintendent of German military hospitals during the Napoleonic Wars (1800–15), and professor of surgery and director of the surgical clinic at the University of Berlin (1810–40), Gräfe’s work revived Tagliacozzi’s “Italian Method,” which used a graft from the upper arm, rather than the forehead.

Prior to this publication, and in the immediate aftermath, plastic surgery was generally understood to be surgery on the nose. However, after publication, there was a surge in the number of “plasties,” as new procedures were all tagged with the suffix. In an attempt to curtail the number of uniquely-named procedures, Eduard Zeis, who is credited with authoring the first textbook on plastic surgery, disavowed the continuous labeling of specific procedures after the model of “rhinoplasty” He adopted Desault’s term, plastic surgery, to encompass all reconstructive procedures to the face and body.

Despite the surgical innovations and writings of these pioneers in plastic surgery, Johann Friedrich Dieffenbach (1792-1847) is widely...
Significant growth and innovation in the field took place during and following the first World War, as the need for reconstructions ballooned.

cited as the “father of plastic surgery.” It was Dieffenbach who used the term “beauty surgery” (today referred to as cosmetic surgery) to differentiate purely aesthetic procedures from “real” reconstructive surgery, which led the movement toward a definitive distinction between the two.

Significant growth and innovation in the field took place during and following the first World War, as the need for reconstructions ballooned. Burn and blast victims, along with those who suffered other disfiguring injuries in the line of battle, presented new challenges to surgeons in the emerging field of reconstructive surgery.

One of the premier surgeons during this time was Sir Harold Delf Gillies, a New Zealander who is famous for his innovative work in the practice of skin grafting and facial reconstructions from gunshot, blast and burn wounds during World War I. Nearly 100 years after Dieffenbach’s contributions revolutionized the field, Gillies is credited as being the “father of modern plastic surgery” for his innovative methods. In a groundbreaking procedure, Gillies reconstructed the face of Walter Yeo, a British sailor, who sustained massive facial burns, as well as the loss of his upper and lower eye lids during the Battle of Jutland in 1916. The relative success of this surgery, and the growing need for similar operations prompted the opening of a new hospital devoted exclusively to facial repairs. (Gillies is also credited with pioneering sex reassignment surgery in the mid-1940s.)

As the practice expanded, a rift grew between reconstructive surgeons, who saw aesthetic surgery as an incidental part of their practice, and cosmetic surgeons, who were accused by the establishment, including Gillies himself, of being, “poorly qualified and very-well advertised surgeons, who adopted the term, plastic surgery, without any true training in surgery and without any other surgical ability than to remove a few folds of skin or a small hump of the nose.” Because of this, “beauty” surgeons were often deemed quacks by their peers.

While the term quack may not be as prevalent today as it once was, the practice of plastic surgery continues to exist in shades of gray. For example, any physician, whether acknowledged as a specialist by his peers or not, can undertake aesthetic surgery. More and more non-board certified physicians perform aesthetic procedures every day, including dentists performing hair transplants.

As physicians’ ability to eliminate pain and reduce the risk of infection grew, the practice of plastic surgery blossomed. The oldest association for aesthetic surgery in the United States is the American Association of Oral Surgeons, which was founded in 1921. It became the American Association of Plastic Surgeons in 1942, and today is known as the American Society of Plastic and Reconstructive
Surgeons, comprising 97 percent of all plastic surgeons certified by the American Board of Plastic Surgery. The board itself was organized in 1937, and admitted to the American Board of Surgery in 1938.

Plastic surgery is a rapidly-growing practice in the United States. In 1981, there were 296,000 reported procedures performed. By 1984, that number had grown to 477,700. In 1996, the American Academy of Facial Plastic and Reconstructive Surgery developed a survey, which revealed that 825,000 plastic and reconstructive procedures had been performed on the face alone in 1995, a nine percent increase from 1993. According to the survey, 65 percent of the procedures performed in 1994 were done on people with a family income of less than $50,000 per year, indicating that financial factors are not a significant deterrent in the decision to aesthetically change one’s body.

In 1997, the total number of all surgical and nonsurgical cosmetic procedures performed in the United States totaled 2,099,173. By 2007, that number had morphed to 11,701,031. These numbers represent a 162 percent increase in the total number of cosmetic procedures. Surgical procedures increased by nearly 80 percent, while nonsurgical procedures increased by more than 233 percent. Nearly 92 percent of all procedures were performed on women. In total, Americans spent nearly $12 billion dollars on cosmetic procedures in 2008.

References

As physicians’ ability to eliminate pain and reduce the risk of infection grew, the practice of plastic surgery blossomed.
Radical Mastectomy and Reconstruction
by Brittany Stapp-Caudell

As thousands of women every year are being diagnosed with breast cancer, bilateral mastectomies are becoming both the prophylactic as well as the therapeutic procedure of choice for women young and old to prevent as well as to combat the aggressive, potentially deadly breast cancers. This article will investigate the indications for mastectomy surgery, as well as a case study of a bilateral modified radical mastectomy in the clinical setting.

INTRODUCTION

In today’s society, the term “mastectomy” is commonplace in medical terminology, as well as in the postings of an operating room’s surgery schedule and insurance billing requests. As thousands of women every year are being diagnosed with breast cancer, bilateral mastectomies are becoming both the prophylactic, as well as therapeutic procedure of choice for women, young and old, to prevent and combat aggressive, potentially deadly, breast cancers.

BREAST ANATOMY

The female breasts are paired anatomical structures on the anterior portion of the thoracic region of a human being. Both males and females have breasts, although the normal anatomy and physiology of the structures varies vastly between the two sexes.

The base of the breast is the attached surface of the breast. It attaches to the deep fascia of the pectoralis major muscle, which overlies the chest cavity. The base of the breast extends vertically over the ribs numbered two through six, and transversally from the sternum to the midaxillary line. The upper region of the breast overlies the chest cavity. The base of the breast extends vertically over the ribs numbered two through six, and transversally from the sternum to the midaxillary line.

LEARNING OBJECTIVES

△ Examine the evolution of the mastectomy procedure
△ Explore the affected anatomy
△ Compare and contrast different surgical options for breast cancer
△ Evaluate the breast cancer staging process
△ Analyze the step-by-step procedure for a bilateral mastectomy
breast can extend as far as the lateral margin of the pectoralis major muscle and into the axilla.

In general, the breasts consist of secretory glands, superficial fascia and overlying skin, and subcuticular fat. Anatomically, in the pectoral region on each side of the anterior thoracic wall, the mammary glands are modified sweat glands in the superficial fascia anterior to the pectoral muscles and the anterior thoracic wall. In each breast, the mammary glands and their associated duct systems are arranged in an array of lobules situated in a circumferential pattern around a central nipple, or papilla. In culmination, the ducts and the lobules converge to form approximately 20 lactiferous ducts that exit separate of one another onto the nipple. Additionally, in relation to breast anatomy, the circular area of pigmented skin immediately surrounding the nipple is referred to as the areola.

In each breast, a developed connective tissue stroma surrounds the individual ductal and lobule systems of the mammary glands. In certain regions, this connective tissue stroma condenses into ligaments. These are the suspensory ligaments of the breast, and are continuous with the dermal and epidermal tissue of the breast. In general, the suspensory ligaments are responsible for supporting the independent structures of the breasts.

The lateral arterial blood supply to the breast provided by the vessels from the superior thoracic axillary artery, the thoracoacromial artery, the lateral thoracic artery and the subscapular arteries. Additionally, the medial breast receives arterial blood flow through the branches from the internal thoracic artery, as well as through the fourth intercostal arteries via arterial branches that perforate the thoracic wall, and the overlying pectoralis musculature. Venous drainage from the breast occurs through veins that parallel the arteries and drain into the axillary, internal thoracic and intercostal veins.

Breast cancers account for about 30 percent of all cancer cases found in women and 16 percent of cancer deaths. The highest rates of breast cancer are in North America and Europe.

through the fourth intercostal arteries via arterial branches that perforate the thoracic wall, and the overlying pectoralis musculature. Venous drainage from the breast occurs through veins that parallel the arteries and drain into the axillary, internal thoracic and intercostal veins.

The normal breast is innervated by a number of nervous branches. Innervation of the breast is via the anterior and lateral cutaneous branches of the second to sixth intercostal nerves. The nipple is innervated by the fourth intercostal nerve.

Nearly 75 percent of the lymphatic drainage of the breast drains laterally and superiorly to the axillary lymph nodes. The remaining lymphatic drainage occurs into the parasternal nodes, as well as through lymphatic vessels that follow the lateral branches of the posterior intercostal arteries. The axillary lymph nodes, therefore, are the primary region to sample for cancer metastasis into the lymphatic system.

In males, the breast anatomy differs greatly. The male breast is a rudimentary system composed of small ducts and strings of breast cells that do not typically extend beyond the areolar region of the male breast.

**Breast Physiology**

The female breast is physiologically responsible for the production of milk for the purpose of nursing an infant. Specifically, the mammary glands are responsible for the production of milk. These glands are present at birth in the female,
yet do not begin developing until puberty. The glands do not become completely functional, however, until the end of pregnancy. Placental lactogen (hPL), a hormone given off by the placenta, prepares the breasts for lactation. Additionally, prolactin, a hormone excreted by the anterior pituitary, stimulates the secretory cells of the breast for lactation. In the male, the breast serves no physiological function.

The initial products of the secretory glands of the breast is termed colostrum and is a thin, white liquid that is “let down” immediately following the birth of a neonate. Milk secretion typically begins within a few days of the birth of a neonate and can extend as long as a few years as long as an infant or toddler is suckling on the breast. The process of an infant suckling the breast acts to remove the created milk and further stimulates additional milk production through the release of Oxytocin, an additional hormone, from the posterior pituitary. In non-lactating women, the predominant component of the breasts is fat, while glandular tissue is more abundant in lactating women.

**Breast Cancer**

Breast cancer is the most common cancer that affects American women today. Additionally, it is the leading cause of death in women ages 40-44 years of age, and is the second most common killer of all ages after lung cancer. The incidence of invasive breast cancer in the female is on the rise, and has increased in incidence since the 1990s. The increase in the incidence rate of invasive breast cancers in today’s society may be a direct result of early detection by means of mammography. Breast cancers account for about 30 percent of all cancer cases found in women and 16 percent of cancer deaths. The highest rates of breast cancer are in North America and Europe.

Breast cancer should be treated as soon as possible, once a firm diagnosis has been made. Early detection and treatment of breast cancer improves the chances of a successful outcome and full recovery. The risk factors of breast cancer can be classified as reproductive, hormonal, environmental and familial, however, the majority of breast cancers occur in women whose only known risk factors are gender and age.

The risk for developing breast cancer in women is affected by her age when her first child is born. The younger a female is when she gives birth to her first child, the lower that particular female’s risk is for developing aggressive and invasive breast cancer.

Additionally, familial factors have an implication in the prevalence of breast cancer development among women. In terms of genetics, breast cancer can be divided into three main groups. The first genetic group is termed sporadic. These women, approximately 40 percent of those diagnosed with breast cancer, have no familial history in the development of the disease. The second group of women has an inherited autosomal-dominant set of cancer-causing genes. The final group is a classification of women who do have a family history, yet do not possess genes that are passed on in a dominant gene fashion.
A history of breast cancer in first-degree relatives (mother or sister) increases a woman’s risk of breast cancer two to three times. The risk of breast cancer in these particular women increases exponentially if there is a history of a second first-degree relative who is suffering or suffered from breast cancer, especially if the disease occurred before menopause, and if the disease was bilateral in fashion. The most common and important of the breast cancer susceptibility genes are the BRAC1 and BRAC2 genes. BRAC1 is located on chromosome 17 and BRAC2 is located on chromosome 13. The BRAC1 and BRAC2 genes are two tumor-suppressing genes that, when mutated, allow a woman to have a higher chance of developing breast cancer.

### SYMPTOMS OF BREAST CANCER

The widespread use of screening mammograms, as well as the overall increase in societal information in relation to breast cancer, has increased the number of breast cancers identified before any symptoms are noticed. There are still, however, some cases in which breast cancers are not diagnosed until certain symptoms become noticed by the patient themselves.

The most common sign of breast cancer is a new lump or mass. A lump felt by either a patient or a health care practitioner that is painless to the touch, hard, and/or has uneven edges is more likely to be cancer when compared to a smoother breast mass. Additional signs of breast cancer include, but are not limited to, swelling of all or a portion of the affected breast, skin dimpling accompanied by breast pain, nipple pain or an inversion of the nipple, redness in the breast region, thickening of the nipple or breast skin, nipple discharge and/or a lump in the axillary regions.

### BREAST CANCER STAGING

Every cancer in the human body is assigned a particular stage. This stage number influences the type of treatment that a patient will receive to treat the cancer. The stage of a given cancer attempts to describe the overall presence and extent of that cancer in the body. The assigned staging number is dependent on a number of factors, including whether or not the cancer is invasive in nature, the size of the cancerous tumor, how many, if any, lymph nodes are involved, as well as whether or not the cancer has metastasized to other regions of the body. In short, staging is the process of determining how widespread a cancer is upon initial diagnosis.

The staging system for cancers acts as a standardized way for the physician team to generalize information about how far a given cancer has spread within the body once diagnosed. In society today, the most common staging system

<table>
<thead>
<tr>
<th>Table 1: Stages of Breast Cancer</th>
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<tbody>
<tr>
<td><strong>PRIMARY TUMOR (T)</strong></td>
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<tr>
<td>TX: Primary tumor cannot be assessed.</td>
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<tr>
<td>T0: No evidence of primary tumor.</td>
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<tr>
<td>Tis: Carcinoma in situ</td>
</tr>
<tr>
<td>T1: Tumor is 2 cm (3/4 of an inch) or less across.</td>
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<tr>
<td>T2: Tumor is more than 2 cm but not more than 5 cm (two inches) across.</td>
</tr>
<tr>
<td>T3: Tumor is more than 5 cm across.</td>
</tr>
<tr>
<td>T4: Tumor of any size growing into the chest wall or skin. This includes inflammatory breast cancer.</td>
</tr>
<tr>
<td><strong>NEARBY LYMPH NODES (N) (based on looking at them under a microscope)</strong></td>
</tr>
<tr>
<td>NX: Nearby lymph nodes cannot be assessed (for example, removed previously).</td>
</tr>
<tr>
<td>N0: Cancer has not spread to nearby lymph nodes.</td>
</tr>
<tr>
<td>N1: Cancer has spread to one to three axillary (underarm) lymph node(s), and/or tiny amounts of cancer are found in internal mammary lymph nodes (those near the breast bone) on sentinel lymph node biopsy.</td>
</tr>
<tr>
<td>N2: Cancer has spread to four to nine axillary lymph nodes under the arm, or cancer has enlarged the internal mammary lymph nodes.</td>
</tr>
<tr>
<td>N3: One of the following applies:</td>
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<tr>
<td>1. Cancer has spread to 10 or more axillary lymph nodes.</td>
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<tr>
<td>2. Cancer has spread to the lymph nodes under the clavicle (collar bone).</td>
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<tr>
<td>3. Cancer has spread to the lymph nodes above the clavicle.</td>
</tr>
<tr>
<td>4. Cancer involves axillary lymph nodes and has enlarged the internal mammary lymph nodes.</td>
</tr>
<tr>
<td>5. Cancer involves four or more axillary lymph nodes, and tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy.</td>
</tr>
<tr>
<td><strong>METASTASIS (M)</strong></td>
</tr>
<tr>
<td>MX: Presence of distant spread (metastasis) cannot be assessed.</td>
</tr>
<tr>
<td>M0: No distant spread.</td>
</tr>
<tr>
<td>M1: Spread to distant organs is present. (The most common sites are bone, lung, brain, and liver.)</td>
</tr>
</tbody>
</table>
is the American Joint Committee on Cancer (AJCC) Tumor Nodal Metastasis (TNM) system. The stage of a breast cancer can be based either on the results of a physical exam, biopsy, and imaging tests (called the clinical stage), or on the results of these tests plus the results of surgery (called the pathologic stage). The TNM staging system classifies the various types of cancers based on the stages of T, the size of the tumor, as well as how far the tumor has spread to nearby anatomical structures; N, the spread of the cancer to the nearby lymph nodes; and M, the level of cancer metastasis to distant organs or structures.

Additional letters and numbers are often seen following the TNM classification. These numbers and letters lend further information regarding the cancer's spread, size and lymphatic association of the cancer. The letter T is typically followed by a number ranging anywhere from zero to four. These numbers describe the size of the tumor, as well as the level of spread to the skin or the chest wall. The higher T numbers describe a larger tumor or a wider spread to tissues surrounding the breast tissue. In addition, the letter N is typically trailed by a number ranging from zero to three. These numbers indicate the degree of cancer spread, if any, to the surrounding lymph nodes and if so, how many lymph nodes are affected. Finally, the letter M is followed by either number zero or one. These numbers indicate whether or not the cancer has metastasized to distant organs or anatomical structures.

Table 1. is taken directly from the American Cancer Society's Web site, and further illustrates the complexity of breast cancer staging that is used in the medical society of today.

**Table 2. Cancer Stages and Survival Rates**

<table>
<thead>
<tr>
<th>Stage</th>
<th>5-year Relative Survival Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>I</td>
<td>100%</td>
</tr>
<tr>
<td>II</td>
<td>86%</td>
</tr>
<tr>
<td>III</td>
<td>57%</td>
</tr>
<tr>
<td>IV</td>
<td>20%</td>
</tr>
</tbody>
</table>

**Diagnostic Study of Breast Cancer**

Breast cancers can be diagnosed through a number of means. Typically, breast masses are felt by palpation, or touch, by either the patient or the health care provider during a routine breast examination. If a breast mass is found, a patient will typically undergo a mammogram study that includes both breasts. The mammogram enables the visualization of dense areas of breast tissues that can diagnose either a malignant or a benign breast mass. Additionally, the mass is usually biopsied to determine whether or not the mass is benign or malignant.

If a malignant mass or masses are found within the breast, a physician may further suggest certain imaging tests such as X-rays, bone scans, CT scans, PET scans or MRI scans in an attempt to help aid in the staging of the cancer, as well as the level, if any, of cancer metastasis. Finally, blood tests and white blood cell counts may be performed on the patient in an attempt to evaluate the overall health of the patient as well as to rule out the complexity of cancer spread.

**Breast Cancer Stage Grouping**

Once the breast cancer has been staged by a physician with the TNM system, the results are further compiled and combined in a process referred to as stage grouping. Cancers with similar stages tend to have a similar outlook and thus are often treated in a similar way. The stage of the diagnosed breast cancer is typically expressed through the use of Roman numerals and varies from stage I, or the least advanced stage of breast cancer, to stage IV, the most advanced stage of breast cancer. A stage of zero refers to a non-invasive cancer.

Table 2. (below), derived directly from the American Cancer Society’s Web site (www.cancer.org), refers to the overall survival rates of treated breast cancers and their respective stages.
TREATMENT OF BREAST CANCERS

Although there has been a noticeable increase in the number of women being affected by breast cancer, there has additionally been an increase in the number of treatment options available to combat the potentially lethal pathology. Today, rather than only one or two options of treatment, a patient diagnosed with breast cancer can opt for a complex mix of treatment options that fight the complex nature of each individual’s breast cancer. A patient can choose from an assortment of surgical treatments, radiation therapy, hormonal therapy and even chemotherapy, or can choose, with the guidance of her health care provider, to attempt a combination of treatment methods to overcome the debilitating cancer.

Surgical treatment of breast cancer is typically the first line of treatment for a patient suffering from breast cancer. Treatments can range anywhere from a lumpectomy to a total bilateral mastectomy. Lumpectomy, also known as breast-conserving surgery, refers to the removal of only the tumor and a small amount of surrounding tissue. In contrast, a mastectomy is the removal of all of the breast tissue. Today, mastectomy surgery is more refined and less intrusive than what the procedure entailed in the past. A typical mastectomy spares the muscles located below the breast unless there has been known cancer metastasis to the area. With both surgical treatments, the patient can additionally choose to have the axillary lymph nodes removed in an attempt to determine whether the aggressive breast cancers have spread into the nearby lymphatic system.

In a less invasive lumpectomy procedure, also known as needle localization and wide excision, a radiologist uses a live mammogram to localize a cancerous area in the breast and then inserts a needle into the cancerous tissue. Following the needle localization, the patient is taken to the operating room, with the needle still in place. During the wide excision portion of the procedure, the needle acts as a locator guide for a surgeon to excise all of the cancerous mass from the breast tissue. In contrast to a mastectomy, a lumpectomy, or needle localization with wide excision, only removes a small volume of breast tissue and thus conserves the relevant anatomy of the breast.

MASTECTOMY

Mastectomy is the medical term for the surgical removal of one or both of the breasts of either a male or a female patient. One or both of the breasts can be partially or completely removed with a mastectomy surgical procedure. Due to the invasive nature of the surgical intervention and the selected means of tissue removal, a mastectomy is considered to be a local therapy when compared to systemic therapies such as chemotherapy, immunotherapy and hormone therapy. Currently, mastectomies are the surgery of choice for both the prophylactic and the therapeutic treatment of all known breast cancers. A mastectomy is not always the most suitable treatment, but in many cases it has proved to be very effective in treating breast cancer.
Although breast cancers are more prevalent in female patients, males can also suffer from the debilitating cancer and thus are also candidates for this procedure.

In the past, it was commonplace in the case of breast cancer to perform a radical mastectomy and remove all of the breast tissues, as well as the underlying musculature and lymphatic drainage system. There are current changes, however, in today’s medical arena in which the election to perform a mastectomy versus a lumpectomy is now based on a number of patient-related factors, such as the size of the patient’s breast, the number of cancerous lesions located within the breast tissue, the overall aggressiveness of the diagnosed breast cancer, as well as patient preference. Outcome studies comparing mastectomy to lumpectomy with radiation have suggested that routine radical mastectomy surgeries will not always prevent later distant secondary tumors arising from micro-metastases prior to discovery, diagnosis, and operation.

**TYPES OF MASTECTOMY**

There are a variety of types of mastectomy procedures being performed in today’s medical community. The type that a patient decides to undergo depends on factors such as size, location, and behavior of the tumor, whether or not the surgery is prophylactic, and whether or not the patient intends to undergo reconstructive surgery following the mastectomy.

A simple mastectomy, also referred to as a total mastectomy, involves the complete surgical removal of the entire breast tissue. The axillary components, however, are left in place. Additionally, this surgery is sometimes done bilaterally as a prophylactic measure on patients who wish to undergo mastectomy as a cancer-preventative measure.

A modified radical mastectomy is an alternative type of mastectomy procedure. When a modified radical mastectomy is performed, the entire affected breast is removed along with the axillary lymph nodes and axillary fat. When compared to a modified radical mastectomy, the pectoralis muscles are left in their proper anatomical location during the modified procedure.

Conversely, a radical mastectomy, sometimes referred to as a “Halstead Mastectomy,” involves the surgical removal of all of the breast tissue, the axillary components as well as the pectoralis major and the pectoralis minor muscles of the chest wall. This procedure is the most invasive and disfiguring mastectomy procedure due to the fact that the patient is left with a large portion of his or her chest removed for the treatment of cancer. Although this type of mastectomy was performed very often in the past, it has since been replaced with the more modified version of the radical mastectomy. The complete radical mastectomy is typically only performed in today’s medical community in extreme cases of breast cancer metastasis that involves the pectoralis muscles.

Mastectomy procedures of today are being further modified to be as minimally-invasive as possible, as well as to provide the patient with some degree of normalcy following the disfiguring surgical procedure. One such modification being performed today is a skin-sparing mastectomy. In this surgery, a conservative areolar incision is made to accommodate the separation of the breast tissue from the overlying skin. This type of mastectomy provides a large pocket of skin that facilitates a breast reconstructive procedure following the mastectomy. As long as the breast tissue is completely separated from the dermis of the skin, the skin can be left without any incidence of cancer metastasis. Patients with cancers that involve the skin, however, are not considered to be candidates for skin-sparing mastectomy.

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Today, rather than only one or two options of treatment, a patient diagnosed with breast cancer can opt for a complex mix of treatment options that fight the complex nature of each individual’s breast cancer.

Similar to a skin-sparing modification of the mastectomy procedure, a subcutaneous mastectomy can be performed in an attempt to preserve the nipple and areola of the patient.

These skin-sparing mastectomies and subcutaneous mastectomies are ideal for patients undergoing prophylactic mastectomies, as well as for patients who wish to undergo an immediate breast reconstructive procedure following the removal of the breast tissue. The benefit of these procedures is that more of the breast skin envelope is preserved to make it easier to recreate the normal anatomical shape of the breast and aids in the psychology of the disfiguring aspect of the mastectomy procedure.
MASTECTOMY INDICATIONS
A patient is recommended to undergo a mastectomy in a number of instances. Some of these specific groups of patients include a patient who has had radiation therapy to the affected breast, a patient suffering from a cancer that is in two or more isolated locations within a single breast, or a patient in whom a lumpectomy failed to completely remove all of the cancerous cells and a cancer reoccurrence has occurred.\(^8\) A mastectomy is additionally recommend-
ed to a pregnant patient who cannot undergo radiation or chemotherapy due to the potential of harming the fetus, patients who have cancerous breast masses larger than two inches in size or, as a prophylactic measure, for patients who have proved to be genetically positive for the BRCA 1 or BRCA 2 gene mutations.\(^8\) Finally, mastectomies are normally indicated for male patients who are diagnosed with breast cancer.

CASE STUDY
The following will investigate a case study of a female patient who had been diagnosed with stage II cancer of the right breast. The patient was a 45-year old Hispanic female. This female patient had a family history of breast cancer and thus had been undergoing mammography visualization of the breast for five years prior to her diagnosis of breast cancer.

In February 2009, a medium-sized mass was felt by the patient during a breast self-exam, and a mammogram was ordered. The mammogram revealed a medium-sized mass confined to the right breast. Additionally, blood samples and an MRI were taken to attempt to determine if the mass was cancerous. Both the MRI and the blood sampling were inconclusive as to whether or not the mass was cancerous and thus, the patient was scheduled for a lumpectomy with sentinel node biopsy. Following the procedure, the mass was removed en bloc, and the sentinel node biopsied. Both specimens were sent to pathology. The breast mass was found to be level II cancer, however, the sentinel lymph node was void of cancer and thus it was determined that the cancer was confined specifically to the breast and had not metastasized to surrounding tissue types.

This patient chose a total, bilateral mastectomy as a means to stop the spread of the aggressive cancer in the right breast, as well as to totally remove the breast tissue of the left breast as a prophylactic measure. After extensive genetic testing due to the patient’s family history of breast cancer, it was found that the patient was positive for the breast cancer BRAC1 and BRAC2 gene mutations following a complete genetic analysis.

PREOPERATIVE PROCEDURE
The patient is placed in the supine position with both arms extended on arm boards. All of the patient’s bony prominences are padded and the feet are placed in padded anti-embolitic compression booties. The anti-embolitic booties both protect the calcaneus, as well as help to aid in venous return to the legs and the prevention of blood clot formation.

A large minor surgical instrumentation set is used for the procedure. Equipment that is needed for a bilateral modified total radical mastectomy includes the following: an electrosurgical pencil with a plume evacuator, attached to the electrosurgical pencil and the suction apparatus. The plume evacuator allows for the removal of the smoke plume that is created through the use of the electrosurgical pencil. Additionally, a Bair Hugger™ warming unit is applied to the patient and a fluid warmer is utilized throughout the procedure to maintain proper body temperature.

In this particular case, the patient had been receiving chemotherapy and radiation therapy prior to the mastectomy surgery, so extra care was taken by the operating room personnel to keep the patient warm. Additionally, care was taken to prevent bruising on areas of the body where bruising could have occurred (padding across the legs where the safety strap was applied, padding around the anti-embolitic hose, etc). Warm blankets were placed over the patient’s arms and legs to aid in temperature regulation following the induction of general anesthesia, and a plastic bag was placed over the patient’s head after the introduction of the endotracheal tube.

The patient’s skin is cleansed with a betadine soap solution and sponges. The soap solution is then allowed to sit on
the skin for five minutes before being wiped off. The umbilicus is cleaned first. The prep starts at each nipple and then the solution is applied in a circular motion, extending outward to the boundaries of the prep area. Once the soap prep is wiped off of the patient’s skin, the surgical region is prepped with DuraPrep™ solution. The skin is prepped from the patient’s chin to the iliac crest and as far laterally as possible.

In order to drape the surgical area, both of the patient’s breasts are outlined with four sterile towels (eight towels total). Following the placement of the sterile towels to outline the incisional areas, a sterile, adhesive laparotomy drape is applied over the breast region of the patient. The drape sheet is extended caudally and handed to the anesthesiologist. It is then extended toward the feet of the patient, creating a sterile field. Following the application of the sterile drapes and the creation of a sterile field, the suction tubing, light handles and ESU surgical pencil are positioned on the sterile field by the surgical technologist in the scrub role.

Prior to the skin incision, a time-out is performed, when the patient’s name, procedure, position, allergies and approach are all stated and agreed upon by participating members of the surgical team. The surgeon is then passed a sterile 10 cc syringe and an 18-gauge needle. The circulating nurse provides an ampule of methylene blue, from which the surgeon draws up 10 cc of the dye. The surgeon is then passed a sterile, 25-gauge needle. The surgeon uses the syringe and hypodermic needle to inject methylene blue dye into the areolar space and nipple of the patient’s affected breast. The dye is taken up by the lymphatic duct system of the breast and outlines the sentinel node.

Once the methylene blue has been injected into the areolar area, 10 ml on a 25 gauge needle of 0.5 percent bupivacaine is passed to the surgeon by the surgical technologist. The drug is in a 10 cc syringe, capped with a 25-gauge hypodermic needle. It is administered for local pain control to the skin and musculature surrounding the intended areolar incision locations.

After the injection of the drugs, a #15 blade, loaded onto a #3 knife handle, is passed to the surgeon. The surgeon creates an areolar incision, which is carried circumferentially around the entire areola. The knife is then passed back to the surgical technologist, who places it on the sterile Mayo stand. The electrosurgical pencil, with suc-
tion attached, is passed to the surgeon. The surgeon uses the electrosurgical pencil to dissect the breast tissue away from the overlying skin extending from the areola down to the fascia of the pectoralis minor muscle. As the dissection is carried deeper into the patient, the surgical technologist anticipates the need of X-ray-detectable sponges, clamps, retractors and pick-ups.

Once the pectoralis muscle is reached, the dissection is then carried laterally to dissect out the sentinel node of the lymphatic system. All breast tissue, with the sentinel lobe attached, is separated from the skin, lymphatic system and underlying musculature. After the complete dissection is complete, the electrosurgical pencil is handed safely back to the surgical technologist, who cleans the tip and places it back into the holster to prevent burns to the patient.

Breast cancer is the most common cancer that affects American women today. Additionally, it is the leading cause of death in women ages 40–44 years of age, and is the second most common killer of all ages after lung cancer.

Once the breast tissue has been dissected, the tissue is removed through the areolar area and handed to the surgical technologist. The surgical technologist labels the specimen on a piece of sterile towel and hands it off to the circulating nurse. The nurse then labels the specimen and immediately takes it to pathology. As the surgery continues, the pathology department personnel examine the sentinel node under the microscope to see if the cancer has metastasized to the lateral margins of the breast. Once the specimen has been carefully examined under the microscope, the pathology department calls the operating room to let the surgeon know if the lateral margins of the breast, as well as the lymphatic system, are indeed clear of the aggressive breast cancer.

In this particular case, the lateral margins of the breast and the lymphatic system showed no signs of the aggressive cancer.

Once the breast specimen is removed, a new #15 blade, loaded onto a #3 knife handle, is handed to the surgeon, who uses it to make a three-inch incision into the fascia between the pectoralis minor and the pectoralis major muscles. Once the incision is made, the patient’s original saline implant is removed by the surgeon and handed to the surgical technologist. The surgical technologist hands the specimen off of the field to the circulator, who places it in a bucket and correctly identifies and labels it. The surgeon then uses the electrosurgical pencil to further open the capsule that has been created by the saline implant. Additional remaining breast tissue is removed and hemostasis is achieved. At the completion of the mastectomy, the wound is irrigated with sterile water to prevent cancer seeding.

All instruments from this point on are considered contaminated as a result of the cancer. A clean set-up is already prepared prior to this portion of the procedure and is utilized for the remaining portions of the procedure on the right, once-cancerous breast. AlloDerm®, a collagen matrix that preserves all the elements necessary for revascularization and cellular repopulation, is placed into the pocket created by the implant/dissection, located within the muscle layers. The material is first soaked in sterile saline for five minutes before it is transferred to another kidney basin full of saline for another five minutes prior to passing to the plastic surgeon. It is then cut to size and placed into the pocket. Non-absorbable sutures are used to keep the graft in place.

Following the insertion of the AlloDerm® into the pocket to create a posterior border to the breast pocket, a sterile tissue expander is passed to the plastic surgeon and placed into the newly-created pocket. A butterfly needle is passed to the surgeon and attached to a sterile, infusible IV tube, attached to a pressurized IV infuser filled with warm saline. The surgeon inserts the butterfly needle into the port on the tissue expander, inflating the tissue expander with 540 cc of warm, sterile saline.

For closure, two Jackson-Pratt drains are placed from the muscle pocket to the outside of the body. A 3-0 silk suture is used to secure the drains in place to the skin. Additionally, absorbable 3-0 polyglactin sutures are passed to the surgeon on a Mayo-Hegar needle holder along with toothed forceps. The sutures are used to close the muscle pocket. Finally, a skin stapler and two Adson, toothed forceps are used to close the areolar incision in a longitudinal fashion.

Following the closure of the right breast, a different, clean set-up is used to carry out the same procedure on the left breast. The sentinel lobe is not removed from the left
side because there is no evidence of cancer present. Only one drain is placed on the left side, which is considered “clean,” due to the fact that it is cancer free. Once the left breast incision is closed with staples, 3-0 undyed polyglec-caprone 25 suture is passed on a Crile-Wood needle holder to close the skin. The staples are removed as individual mattress sutures are placed, and then a continuous running suture is placed to close the skin incisions on both sides. Straight Mayo scissors are used to cut the suture edges.

After complete closure on both sides, one-inch wound-closure strips are applied over the incisional area. A wet towel is used to clean the breast and abdominal areas, followed by a dry towel to dry the breast and abdominal area. Two sterile, abdominal pads are placed over the skin incision site, the drapes are removed and the ABD pads are secured with a bandeau-style wrap. Finally, the patient is taken off of anesthesia and extubated. Following extubation, the patient is transported to the post-anesthesia care unit.

Complications of the total bilateral modified radical mastectomy include bleeding, infection, reactions to anesthesia, adhesion formations, thrombi or emboli formation, cancer metastasis, psychological disfigurement problems and death. Additionally, the patient undergoing a radical mastectomy may additionally suffer from phantom breast pain, swelling of the breast area and the possibility of seroma formation. Complications to the tissue expanders include, but are not limited to, infection, bleeding, rupture of implants, dimpling of the skin as well as visualization impedance during follow-up return mammograms.

The advantage to immediate breast reconstruction, as this particular patient opted for, include not waking up to the trauma of losing the anatomical look of the breasts and eliminating the need for additional reconstructive surgery.

ABOUT THE AUTHOR

Brittany Stapp-Caudell is working as a surgical technologist at Community Regional Medical Center in Fresno, California. She graduated from the surgical technology program at San Joaquin Valley College in Fresno, in September 2009, and is currently awaiting the results of her certification examination.

References

Additional Resources

AlloDerm is a trademark of LifeCell Corp.
Bair Hugger is a trademark of Arizant Inc.
DuraPrep is a trademark of 3M.
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Wrist fusion

1. Diagnosis of rheumatoid arthritis does not involve:
   a. Reviewing family history
   b. Examining joints for inflammation and deformity
   c. Blood tests
   d. Stress tests

2. A/an __________ utilizes a sterile needle and syringe to drain joint fluid.
   a. Arthrocentesis
   b. Arthroscopy
   c. Spinal tap
   d. Synovectomy

3. __________ develops during the early, acute inflammatory stage.
   a. Subluxation of the ulna
   b. Intrinsic contracture
   c. Fixed DRUJ
   d. Bony compression

4. ___________ bones are the long bones in the palm.
   a. Phalanges
   b. Trapezium
   c. Carpal
   d. Metacarpal

5. The proximal row does not include the:
   a. Scaphoid
   b. Lunate
   c. Trapezoid
   d. Pisiform

6. The ________ coordinates the movement of the distal and proximal rows.
   a. Radius
   b. Scaphoid
   c. Hamate
   d. Carpal

7. Carpal bones connect the __________ and __________ to the bones in the hand.
   a. Capitate and trapezium
   b. Scaphoid and pisiform
   c. Radius and ulna
   d. Trapezoid and lunate

8. Second-line drugs include all but:
   a. Cortisone
   b. Methotrexate
   c. Gold salts
   d. Adalimumab

9. If the __________ is not fused, a patient will have continued rotation in the hand.
   a. Radius
   b. Hamate
   c. Ulna
   d. Lunate

10. Fusing wrist bones together may:
    a. Prevent deformity
    b. Eliminate pain
    c. Improve alignment
    d. All of the above
11. The intraoperative phase of a wrist fusion begins with a:
   a. Dissection down the extensor retinaculum
   b. Opening of the radiocarpal joint
   c. Dorsal, longitudinal incision over Lister tubercle
   d. Synovectomy

12. Types of NSAIDS are:
   a. Salicylates
   b. Traditional NSAIDS
   c. Cox-2 selective inhibitors
   d. All of the above

13. Prostaglandins do all but:
   a. Promote inflammation
   b. Facilitate the function of blood platelets
   c. Protect the stomach lining
   d. Halt joint damage

14. Disease-modifying anti-rheumatic drugs are effective in:
   a. Rheumatoid arthritis
   b. Psoriatic arthritis
   c. Ankylosing spondylitis
   d. All of the above

15. ____________ is a hormone produced in the adrenal gland.
   a. Calcitonin
   b. Thyroxine
   c. Cortisol
   d. GnRh

16. Steroids are used to alleviate:
   a. Lupus
   b. Rheumatoid arthritis
   c. Vasculitis
   d. All of the above

17. ____________ stimulate or restore the ability of the immune system to fight disease or infection.
   a. Analgesics
   b. Corticosteroids
   c. BRMs
   d. Cox-2

18. ____________ block the Cox enzymes and reduce prostaglandins.
   a. Steroids
   b. Analgesics
   c. BRMs
   d. NSAIDS

19. Which of the following agents is commonly applied to the bleeding surface and edges of bone?
   a. Bone wax
   b. Thrombin
   c. Avitene
   d. Bacitracin

20. For the wrist fusion procedure, the patient was placed in the supine position. What muscles are relaxed by the small pad under the patient’s head?
   a. Deltoid
   b. Pyramidal
   c. Strap
   d. Cremaster

Mark one box next to each number. Only one correct or best answer can be selected for each question.
1. Health care workers should be cautious when prescribing opioids to __________.
   a. Transplant recipients
   b. Cardiac patients
   c. Diabetic patients
   d. Recovering addicts

2. One component of pain is __________.
   a. Physical c. Pain scale
   b. Pre-existing d. Opioids

3. The emotional components of pain include:
   a. Anger
   b. Sadness
   c. Depression
   d. All of the above

4. Acute pain in postoperative surgical patients is due to:
   a. Emotional distress
   b. Pre-existing disease
   c. Surgical procedure
   d. A combination of B and C

5. __________ leads to a rise in heart rate, increased oxygen consumption and overall cardiac workload.
   a. Opioid prescription
   b. Unrelieved pain
   c. Arterial blockage
   d. Intoxication

6. __________ is a chronic, relapsing and treatable disease characterized by lack of control over consumption and compulsive use despite harmful consequences.
   a. Addiction
   b. Diabetes
   c. Crohn's
   d. Arthritis

7. The most important step in proper postoperative pain management is:
   a. Administration of prescription drugs
   b. Maintaining the dopamine pathway
   c. Proper preoperative assessment
   d. Understanding and treating a patient's addiction

8. An example of a pain assessment tool is a:
   a. Numeric Scale
   b. Visual analog scale
   c. Picture scale
   d. All of the above

9. A patient's altered level of consciousness in the acute postoperative phase of care due to intraoperative anesthetics makes it hard to successfully administer:
   a. An IV drip
   b. Oral analgesics
   c. A pain assessment
   d. All of the above

10. Physical indications of pain in the acute postoperative setting include:
    a. Sweating
    b. Elevated heart rate
    c. Trouble moving/taking deep breaths
    d. All of the above
11. One way to help ensure postoperative pain management for a patient with a history of opioid addiction is:
   a. Obtain a preoperative substance abuse history
   b. Consult an addictionologist
   c. Administer frequent pain scale tests
   d. Begin a preoperative pain management regimen

12. Which of the following is not an alternative pain treatment?
   a. Electro-shock therapy
   b. Local and regional anesthesia
   c. Epidural blocks
   d. Local pain pumps

13. Postoperative fears for opioid-dependent patients may include:
   a. Being judged by the care giver
   b. Suffering a relapse into drug use
   c. Not receiving enough pain medication
   d. All of the above

14. Blocking the action of cyclooxygenase and inhibiting prostaglandin production can be accomplished with:
   a. Steroidal treatment
   b. A Clonodine patch
   c. NSAID therapy
   d. All of the above

15. ________ is a synthetic narcotic used to treat opioid addiction.
   a. Heroin
   b. Clonodine
   c. Methadone
   d. Prednisone

16. Methadone is used in the treatment of addiction to:
   a. Opiates
   b. Alcohol
   c. Methamphetamine
   d. All of the above

17. Side effects of Methadone use include:
   a. Impairs cognitive functions
   b. Debilitating drowsiness
   c. Liver damage
   d. Methadone has no serious side effects

18. Opiates provide a flood of ________, which causes the euphoric high associated with drug use.
   a. Epinephrine
   b. Dopamine
   c. Endorphins
   d. Morphine

19. The preoperative assessment for a substance abuser should include:
   a. The patient’s drug history
   b. The patient's recovery history
   c. A full physical
   d. All of the above

20. Patients who take opiates in large doses have a higher ________.
   a. Pain threshold
   b. Drug-seeking behavior
   c. Tolerance
   d. All of the above

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Pain management for patients with a substance abuse history

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Mark one box next to each number. Only one correct or best answer can be selected for each question.
Drug discovery, development and approval processes

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1. The drug sildenafil citrate (Viagra®) was originally developed to treat ____.  
   a. Angina  
   b. Erectile dysfunction  
   c. Hypertension  
   d. Glaucoma

2. A drug containing active molecules that have never been included in another new drug application is called _______.  
   a. A new molecular entity  
   b. An original compound  
   c. A unique chemical compound  
   d. A prototype

3. Which is not a principal concept affecting drug interaction?  
   a. Onset  
   b. Peak effect  
   c. Duration of action  
   d. Frequency of future doses

4. ______ studies encompass the entire process of the drug within the body.  
   a. Toxicology  
   b. Pharmacokinetic  
   c. Post-clinical  
   d. Biotransformation

5. ______ studies determine the dosage and safety of the drug for human use.  
   a. Toxicology  
   b. Pharmacokinetic  
   c. Post-clinical  
   d. Biotransformation

6. Toxicology studies are used to determine:  
   a. Toxic, side and adverse effects  
   b. Reversal agents  
   c. Addictive properties  
   d. All of the above

7. ______ denotes a study when subjects and administrators are unaware of grouping status.  
   a. Single blind  
   b. Double blind  
   c. Placebo  
   d. None of the above

8. A written plan of action that follows the scientific process is a _______.  
   a. Theory  
   b. Hypothesis  
   c. Protocol  
   d. Trial

9. Examples of clinical safeguard trials include:  
   a. Informed Consent  
   b. Audits  
   c. Institutional review boards  
   d. All of the above

10. Human trials have _____ phases.  
    a. 2  
    b. 3  
    c. 4  
    d. 5
11. The ______ contains all information known about a new drug.
   a. New drug application (NDA)
   b. Food and drug administration (FDA)
   c. Center for drug evaluation and research (CDER)
   d. Center for disease control (CDC)

12. A patent is valid for _____ years from the original date of application.
   a. 10  c. 20
   b. 15  d. 25

13. A ______ distinguishes the source of goods of one party from those of another.
   a. Phrase
   b. Symbol
   c. Design
   d. Trademark

14. A new drug application is filed with the FDA at the end of______.
   a. Phase 1  c. Phase 3
   b. Phase 2  d. Phase 4

15. ____ is conducted on a small group of people (20-80).
   a. Phase 1  c. Phase 3
   b. Phase 2  d. Phase 4

16. Determining effectiveness and identifying long-term risks are purposes of _____.
   a. Phase 1  c. Phase 3
   b. Phase 2  d. Phase 4

17. The study design for ____ trials is usually a double blind, randomized control trial.
   a. Phase 1  c. Phase 3
   b. Phase 2  d. Phase 4

18. Approximately how many clinical trials are currently underway worldwide?
   a. 50-55,000
   b. 55-60,000
   c. 60-65,000
   d. 65-70,000

19. One of the biggest legal challenges in clinical trials is _____________.
   a. Luring qualified volunteers
   b. Misrepresentation/fraud
   c. Clarity of informed consent
   d. FDA regulations and safeguards

20. Increasing legal threats may lead to a decline in _____________.
    a. Quality of medical research
    b. Willing volunteers
    c. Clinical trials
    d. Marketable drugs
Wound Management

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1. Failure of a wound to heal can result in ____.
   a. Additional surgical procedures
   b. Longer hospital stays
   c. Long-term disability
   d. All of the above

2. A full thickness surgical incision will be repaired by ________.
   a. Primary intention
   b. Secondary intention
   c. Polylactin suture
   d. Adhesive strips

3. Regeneration and repair of a pressure ulcer is an example of ________.
   a. Primary intention
   b. Secondary intention
   c. Granulation
   d. Epithelialisation

4. The proliferation phase of healing includes ________.
   a. Inflammation
   b. Contraction
   c. Maturation
   d. B&C

5. The cessation of bleeding following an injury is ________.
   a. Contraction
   b. Proliferation
   c. Hemostasis
   d. Maturation

6. ________ is classified as the early inflammatory stage of wound healing.
   a. Contraction
   b. Proliferation
   c. Hemostasis
   d. Maturation

7. ________ may be regarded as the first line of defense against infection at the wound site.
   a. Neutrophil leucocytes
   b. Basophils
   c. Eosinophils
   d. Monocytes

8. The class of compounds known as ________ are vital for cell-to-cell and tissue adhesion.
   a. Fibroblasts
   b. Proteoglycans
   c. Electrolytes
   d. Glycoproteins

9. By keeping a wound moist, ________.
   a. Infection is more likely
   b. Healing time is prolonged
   c. Healing rates increase
   d. Scarring is increased

10. Spillage of bile during a cholecystectomy is classified as a ________ wound.
    a. Clean
    b. Clean/Contaminated
    c. Contaminated
    d. Dirty/Infected

Wound Management

PART 1 OF 2

Mark one box next to each number. Only one correct or best answer can be selected for each question.
11. One intrinsic factor affecting wound healing is __________.
   a. Wound perfusion
   b. Radiotherapy
   c. Medication
   d. Wound infection

12. One extrinsic factor affecting wound healing is __________.
   a. Disease
   b. Age
   c. Oxygen tension
   d. Radiotherapy

13. Surgical patients should eat within _____ of surgery for optimal clinical outcome.
   a. 6
   b. 12
   c. 24
   d. 48

14. ________ is a critical nutrient in optimizing the tensile strength of new tissue.
   a. Carbohydrate
   b. Protein
   c. Fat
   d. Vitamin A

15. ________ is a critical nutrient for collagen synthesis.
   a. Vitamin A
   b. Vitamin E
   c. Vitamin B
   d. Vitamin K

16. ________ is another critical nutrient for collagen synthesis
   a. Iron
   b. Zinc
   c. Vitamin C
   d. All of the above

17. Attributes of a surgical dressing include the ability to __________.
   a. Enable gaseous exchange
   b. Maintain a dry environment
   c. Compress the wound
   d. Adhere to the skin

18. Low-cost, transparent adhesive film dressings are ideal for __________.
   a. Infected wounds
   b. Straight forward surgical wounds
   c. Acute surgical wounds
   d. Nonsurgical wounds

19. Factors to consider when selecting a wound dressing include __________.
   a. Level of exudates
   b. Depth of the wound
   c. Cost
   d. All of the above

20. A mild to moderate amount of exudate requires a __________ dressing.
   a. Alginate
   b. Simple adhesive film
   c. Hydrocolloid dressing
   d. Adhesive film/foam

Mark one box next to each number. Only one correct or best answer can be selected for each question.
Maslow’s Hierarchy of Needs

1. Maslow developed the concept for the hierarchy of needs by observing _______.
   a. Kurt Goldstein  c. Monkeys
   b. His students  d. Infants

2. Based on observed reactions, the most important need in monkeys is_______.
   a. Water  b. Food  c. Play  d. None of the above

3. The _______ level of the pyramid addresses the need of being.
   a. Safety needs  b. Self-actualization  c. Psychological needs
   d. Physiological needs

4. _______ needs make up the four lower components of Maslow’s pyramid.

5. Drawing conclusions about spirituality is an example of _______ needs.

6. Needs that must occur for the body to survive are _______ needs.
   a. Safety  c. Belongingness
   b. Esteem  d. Physiological

7. The body regulates itself by _______.
   a. Controlling its temperature  b. Counterbalancing hormones
   c. Homeostasis  d. All of the above

8. Fear can prevent an individual from fulfilling _______ needs.
   a. Esteem  b. Belongingness  c. Safety
   d. Physiological

9. Belongingness needs can be influenced by _______.
   a. Socially-accepted behaviors  b. Education levels
   c. Economic status  d. All of the above

10. According to Maslow, a child who grows up in an affluent neighborhood is _______ likely to join a gang.

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Name __________________________________________
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Mark one box next to each number. Only one correct or best answer can be selected for each question.
11. The highest platform in the category of deficit needs is ________.
   a. Physiological  c. Esteem
   b. Belongingness  d. Safety

12. Self-esteem begins to manifest at ________.
   a. Age 2  b. Age 5  c. Age 12  d. Birth

13. The lower form of self-esteem is characterized by ________.
   a. A need to be respected by others
   b. A low opinion of oneself
   c. Confidence in one's abilities
   d. Inferiority complexes

14. The higher form of self-esteem is characterized by ________.
   a. A need to be respected by others
   b. A low opinion of oneself
   c. Confidence in one's abilities
   d. None of the above

15. Low self-esteem is characterized by ________.
   a. Constantly seeking validation/acceptance
   b. Lack of self-respect
   c. Unrealistic expectations for oneself
   d. All of the above

16. “The single component of being” describes ________.
   a. High self-esteem
   b. Self-actualization
   c. Social acceptance
   d. Maslow’s Hierarchy of Needs

17. Fluctuation within Maslow’s hierarchy is ________.
   a. Common  c. Constant
   b. Probable  d. All of the above

18. The process of self-actualization can include ________.
   a. Defining oneself spiritually
   b. Focusing on resolving deficits
   c. Rejecting unfavorable aspects of one’s life
   d. A & B

19. Self-actualization is limited to ________.
   a. Dignitaries
   b. Everyone
   c. Scientists
   d. Explorers

20. Maslow’s Hierarchy of Needs is especially relevant in the ________ field.
   a. Medical
   b. Educational
   c. Self-help
   d. All of the above
Endoscopic Thoracic Sympathectomy

309 September 2009 2 CE credits

1. ETS was initially developed to treat
   _____________.
   a. Goiter
   b. Glaucoma
   c. Epilepsy
   d. All of the above

2. The ___________ is responsible for controlling involuntary bodily functions.
   a. Autonomic nervous system
   b. Central nervous system
   c. Regulatory system
   d. Homeostatic effect

3. The _____ system slows down a function.
   a. Homeostatic c. Parasympathetic
   b. Sympathetic d. Autonomic

4. The “fight or flight” response is triggered by the _______ system.
   a. Homeostatic c. Parasympathetic
   b. Sympathetic d. Autonomic

5. The _______ are destroyed during the ETS procedure.
   a. Sympathetic trunk
   b. Sympathetic ganglia
   c. Spinal nerves
   d. None of the above

6. ETS is a treatment for ____________.
   a. Hyperhydrosis
   b. Epilepsy
   c. Irregular heartbeat
   d. All of the above

7. Treatment options for idiopathic craniofacial erythema include ________.
   a. Endoscopic thoracic sympathectomy
   b. Valium
   c. Cognitive behavioral therapy
   d. All of the above

8. ___________ is a vascular disorder that affects blood flow to extremities in cold conditions.
   a. Erythromelalgia
   b. Raynaud’s Syndrome
   c. Complex regional pain syndrome
   d. Hypoxia

9. Raynaud’s Syndrome can result in ____________.
   a. Gangrene c. Skin atrophy
   b. Skin ulcers d. All of the above

10. Thermography and radiography are two methods of detecting ______.
    a. Erythromelalgia
    b. Raynaud’s Syndrome
    c. Complex regional pain syndrome
    d. Hypoxia

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ENDOSCOPIC THORACIC SYMPATHECTOMY PART 1 OF 2 309 September 2009 2 CE credits

Mark one box next to each number.
Only one correct or best answer can be selected for each question.
11. Clamping the nerves allows for ________.
   a. Irreversible procedure
   b. Temporary relief
   c. Improved functionality
   d. Easier reversal process

12. A _______ is not used in the ETS procedure.
   a. Harmonic scalpel
   b. Hemostat
   c. Video tower
   d. Fiber-optic light source

13. Complications associated with ETS sometimes include ________.
   a. Respiratory problems
   b. Compensatory sweating
   c. Horner's Syndrome
   d. All of the above

14. Disfiguring asymmetry of the face can indicate ________.
   a. Raynaud's Syndrome
   b. Horner's Syndrome
   c. Erythromelalgia
   d. Complex regional pain syndrome

15. A reversal of the ETS procedure is possible by ________.
   a. Performing a nerve graft
   b. Removing the clip from the nerve
   c. A or B, depending on the surgeon's method
   d. The ETS procedure is not reversible

16. Erythromelalgia cannot be described as ________.
   a. Idiopathic
   b. A rare disease
   c. A curable disease
   d. A & B

17. _______ can trigger an EM flare-up.
   a. Heat
   b. Physical activity
   c. Anger
   d. A & B

18. EM can develop due to ________.
   a. Psychological disorders
   b. Neurologic or blood disorders
   c. Physical contact with a carrier
   d. A & B

19. ________ do not blush in social situations.
   a. Babies
   b. Cognitive-behavioral therapy patients
   c. ETS recipients
   d. Everyone blushes

20. Cognitive-behavioral therapy can include ________.
   a. Rational emotive behavior therapy
   b. Dialectic behavior therapy
   c. Cognitive therapy
   d. All of the above
In-Office Autologous Fat Grafting

1. Plastic surgery most often addresses which of Maslow’s needs?
   a. Physiological
   b. Safety
   c. Love and belonging
   d. Prestige and esteem

2. The most common facial locations for autologous fat grafting include _______.
   a. Nasolabial folds
   b. Chin
   c. Marionette grooves
   d. All of the above

3. Which of the following does not describe an autologous fat graft?
   a. Safe
   b. Permanent
   c. Temporary
   d. Reversible

4. The ultimate goal of cosmetic surgery is ___________.
   a. Help the patient achieve a positive self-evaluation
   b. Fix the patient’s physical short-comings
   c. Create a new image for the patient
   d. Reverse the affects of aging

5. Patients who have undergone _________ are not good candidates for autologous fat grafting.
   a. Oral surgery
   b. Organ transplant
   c. Abdominal surgery
   d. All of the above surgery

6. The choice of anesthetic for cosmetic procedures depends on ___________.
   a. The patient’s health
   b. The number of procedures being performed
   c. The patient’s current medications
   d. All of the above

7. In a fat grafting procedure, the _________ are filled first.
   a. Nasolabial folds
   b. Cheeks
   c. Jaw line
   d. None of the above

8. Nose reconstructions are believed to have been performed as early as _________.
   a. 2,000 BCE
   b. 600 BCE
   c. 1880
   d. The Middle Ages

9. Who is the considered the father of plastic surgery?
   a. Pierre Joseph Desault
   b. Karl Ferdinand von Graefe
   c. Johann Friedrich Dieffenbach
   d. Sir Harold Gillies

10. Most cosmetic surgery cases are performed under ___________.
    a. Local anesthetic
    b. IV with sedation
    c. General anesthesia
    d. Acetaminophen

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11. Alternative options for facial augmentation include _______.
   a. Botox    c. Injectable fillers
   b. Chemical peels  d. All of the above

12. The term “plastic” is derived from a/an _____ word.
   a. Indian    c. Latin
   b. Greek     d. Sanskrit

13. For facial procedures, the patient is put in the _______ position.
   a. Trendelenburg
   b. Supine
   c. Reverse Trendelenburg
   d. Fowler’s

14. Who was a leading pioneer in skin grafts and sex-reassignment surgery?
   a. Gasparo Tagliacozzi
   b. Karl Ferdinand von Graefe
   c. Johann Friedrich Dieffenbach
   d. Sir Harold Gillies

15. After the fat is harvested, the next step is to _______.
   a. Inject the donor fat into the specified areas
   b. Place the syringes in a centrifuge
   c. Apply a cold compress to the surgical site
   d. Cleanse the injection site

16. Cosmetic surgery became popular during the Renaissance due to _______.
   a. Syphilis    c. Social pressures
   b. Nose amputation  d. All of the above as punishment

17. The oldest association for aesthetic surgery in the United States is the _____.
   a. American Academy of Facial Plastic and Reconstructive Surgery
   b. American Association of Plastic Surgeons
   c. American Association of Oral Surgeons
   d. American Board of Plastic Surgery

18. The term “plastic surgery” was coined by ___________.
   a. Pierre Joseph Desault
   b. Karl Ferdinand von Graefe
   c. Johann Friedrich Dieffenbach
   d. Sir Harold Gillies

19. From 1997 to 2007, the number of cosmetic procedures in the United States increased _______.
   a. 162 percent    c. 92 percent
   b. 233 percent    d. 80 percent

20. The father of modern plastic surgery is ____________.
   a. Pierre Joseph Desault
   b. Karl Ferdinand von Graefe
   c. Johann Friedrich Dieffenbach
   d. Sir Harold Gillies

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IN-OFFICE AUTOLOGOUS FAT GRAFTING  PART 2 OF 2

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Radical Mastectomy and Reconstruction

1. Breast(s) consist generally of _______ .
   a. Secretory glands  
   b. Subcuticular fat  
   c. Overlying skin  
   d. All of the above

2. _______ are modified sweat glands.
   a. Breasts  
   b. Mammary glands  
   c. Nipples  
   d. Superficial fascia

3. _______ compose the suspensory ligaments of the breast.
   a. Connective tissue stroma  
   b. Individual ductal and lobule systems  
   c. Dermal tissues of the breast  
   d. None of the above

4. The lateral arterial blood supply to the breast does not include the _______.
   a. Fourth intercostal artery  
   b. Thoracoacromial artery  
   c. Lateral thoracic artery  
   d. Superior thoracic axillary artery

5. Nearly ______ percent of lymphatic drainage of the breast drains laterally and superiorly to the axillary lymph nodes.
   a. 65  
   b. 70  
   c. 75  
   d. 80

6. The _______ are the primary region to sample for cancer metastasis into the lymphatic system.
   a. Parasternal lymph nodes  
   b. Axillary lymph nodes  
   c. Lymphatic vessels  
   d. Intercostal veins

7. The mammary glands are completely functional at _______.
   a. Puberty  
   b. The end of pregnancy  
   c. Birth  
   d. Conception

8. hPL is a hormone given off by the _______.
   a. Placenta  
   b. Pituitary gland  
   c. Secretory glands  
   d. None of the above

9. _______ is the leading cause of death in women aged 40–44.
   a. Heart disease  
   b. Lung cancer  
   c. Breast Cancer  
   d. None of the above

10. The risk of developing breast cancer is related to _______.
    a. Age when first child is born  
    b. Genetic factors  
    c. Family history  
    d. All of the above

Mark one box next to each number. Only one correct or best answer can be selected for each question.
11. _____ stimulates the secretory cells for lactation.
   a. Placental lactogen
   b. Prolactin
   c. Oxytocin
   d. B & C

12. Breast cancers account for _____ percent of all cancers in women and _____ percent of cancer deaths.
   a. 30, 16
   b. 43, 30
   c. 16, 30
   d. 43, 16

13. _____ provides a standardized way for physicians to determine information about a cancer's metastasis.
   a. Staging
   b. Mammogram
   c. Lumpectomy
   d. None of the above

14. The most common staging system is the _____.
   a. Mammogram
   b. Lumpectomy
   c. Tumor Nodal Metastasis
   d. None of the above

15. Pathological staging includes the results of a _____.
   a. Mammogram
   b. Lumpectomy
   c. Tumor Nodal Metastasis
   d. None of the above

16. Patients have many treatment options, including _____.
   a. Radiation therapy
   b. Chemotherapy
   c. Hormonal therapy
   d. All of the above

17. In TNM classification, the number following a T indicates _____.
   a. Size of the tumor
   b. If the cancer has metastasized
   c. If the cancer has spread to the lymph nodes
   d. All of the above

18. _____ is considered a “breast-conserving surgery.”
   a. Mastectomy
   b. Breast reconstruction
   c. Needle localization and wide excision
   d. B & C

19. In a _____, the surgeon removes a small volume of breast tissue.
   a. Mastectomy
   b. Breast reconstruction
   c. Lumpectomy
   d. B & C

20. Removal of one or both breasts in a male or female patient is a _____.
   a. Mastectomy
   b. Breast reconstruction
   c. Lumpectomy
   d. Needle localization and wide excision

RADICAL MASTECTOMY AND RECONSTRUCTION  PART 2 OF 3

Mark one box next to each number. Only one correct or best answer can be selected for each question.
21. An example of a minimally-invasive procedure is a ____________.
   a. Simple mastectomy  
   b. Skin-sparing mastectomy  
   c. Halstead mastectomy  
   d. A & B

22. Methylene blue is used during a mastectomy to ____________.
   a. Sterilize the surgical site  
   b. Provide local anesthetic  
   c. Outline the sentinel node  
   d. None of the above

23. The complete removal of the entire breast tissue is a ____________.
   a. Simple mastectomy  
   b. Radical mastectomy  
   c. Modified radical mastectomy  
   d. Halstead mastectomy

24. A/an ____________ is used to separate the breast tissue from the skin.
   a. Electrosurgical pencil  
   b. #15 blade  
   c. Harmonic scalpel  
   d. None of the above

25. In a TRAM flap reconstruction, the surgeon reconstructs the breasts with ____________.
   a. Warm saline  
   b. Autologous fat  
   c. AlloDerm®  
   d. Artificial fillers

26. Axillary components and the pectoralis muscles are removed in a ____________.
   a. Simple mastectomy  
   b. Radical mastectomy  
   c. Modified radical mastectomy  
   d. Bilateral mastectomy

27. To prevent cancer seeding, the wound is ____________.
   a. Cauterized  
   b. Closed with absorbable suture  
   c. Irrigated with sterile water  
   d. All of the above

28. Complications of a mastectomy include ____________.
   a. Infection  
   b. Disfigurement  
   c. Cancer metastasis  
   d. All of the above

29. In a modified radical mastectomy, ____________ are removed.
   a. Only axillary components  
   b. Axillary components & pectoralis muscles  
   c. Both breasts, in their entirety  
   d. Only suspicious lumps

30. Specimens from mastectomy patients are examined ____________ by the pathology department.
   a. Prior to scheduling surgery  
   b. Intraoperatively  
   c. Postoperatively  
   d. At follow-up appointments

RADICAL MASTECTOMY AND RECONSTRUCTION  PART 3 OF 3

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### Wrist Fusion: Fighting back against rheumatoid arthritis

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### Pain management for patients with a substance abuse history

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### Drug Discovery: Development and approval processes

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### The Role of the Surgical Technologist in Wound Management

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### Maslow’s Hierarchy of Needs

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### A Surgical Cure for Chronic Blushing: Endoscopic Thoracic Sympathectomy

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### Factial Plastic Surgery: Autologous Fat Grafting

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### Radical Mastectomy and Reconstruction

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**Mark one box next to each number. Only one correct or best answer can be selected for each question.**

**Directions:** Complete all 8 answer keys for the exams. Include your check or money order made payable to AST or complete credit card information with the appropriate amount and mail to Members Services, AST, 6 W Dry Creek Circle, Ste 200, Littleton, CO 80120-8031. If paying by credit card, you can fax in the answer keys and credit card payment to AST at 303-694-9169.