# clevelandclinicmagazine

summer 2007

## Beyond Minimally Invasive

New Hope for High-Risk Heart Patients

pg. 12

## TOP TEN MEDICAL INNOVATIONS OF 2007

pg. 25

HOW TO EAT CHOCOLATE pg. 8

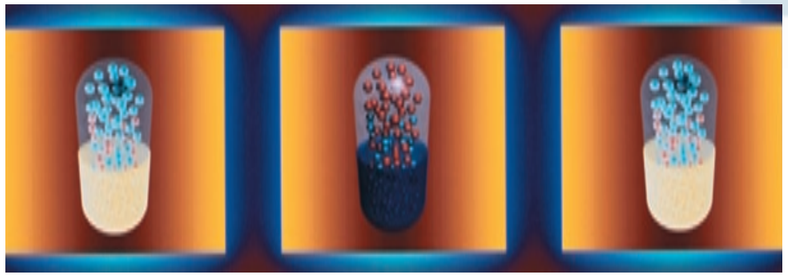
FREEDOM FROM INCONTINENCE pg. 18

clevelandclinicmagazine

# contents

volume 4 issue 2 • summer 2007







Cover illustration by Bryan Christie

## DEPARTMENTS



ontheweb pg. 11
clevelandclinic.org/ccm
Take our readers' poll and find expanded coverage on the stories in this issue.



Cleveland Clinic

clevelandclinic.org/ccm



Questions, comments and subscription requests:

Managing Editor
*Cleveland Clinic Magazine*
Cleveland Clinic / W14
9500 Euclid Ave.
Cleveland, OH 44195

clevelandclinicmagazine@ccf.org
216.444.8255

*Cleveland Clinic Magazine* is a biannual publication of Cleveland Clinic.  Printed in the United States. Periodicals postage paid at Cleveland, Ohio. The magazine accepts no unsolicited manuscripts, photography or artwork. Send change of address to Managing Editor, *Cleveland Clinic Magazine*, Cleveland Clinic / W14, 9500 Euclid Ave., Cleveland, OH 44195.





# A Better Patient Experience

A Letter to Our Readers from Delos M. Cosgrove, M.D., CEO and President

Being CEO of a major academic medical center constantly invites new challenges. Some challenges can be anticipated, while others come straight out of left field. These latter challenges are the ones that often hit the hardest, but can have the greatest impact. Not long ago, I had an experience that presented such a challenge.

I was invited to Harvard Business School to discuss a case study on Cleveland Clinic. After a very positive and stimulating first session, a student at the second session raised her hand and said, "Dr. Cosgrove, my father needed mitral valve surgery. We knew about Cleveland Clinic and the excellent results you had. But we decided not to go because we heard you had no empathy there. We went to another hospital instead."

The student then asked me: "Dr. Cosgrove, do you teach empathy at Cleveland Clinic?" The question left me speechless.

I've thought a great deal about this incident since then. Here at Cleveland Clinic, we've always positioned quality in terms of outcomes. But I have come to understand that there is more to quality healthcare than great outcomes. There is the entire experience that patients have, from the moment they call for an appointment to the moment they arrive at the hospital — fearful and concerned — to the moment they get in their cars and drive away.

The patient experience encompasses many aspects of care, from the physical environment to the emotional. It is about having rooms that are clean. It is about having people who smile and greet patients at every corner of the hospital. It is about communication and the expression of care and concern at times when they are most needed.

Sometimes we forget that patients feel cold in the operating room and could use a warm blanket. Or we forget that they might be hungry at a time when no food is being served. We can no longer do that. We must be aware of patients' needs from the very moment they entrust us with their care. Everything we do must communicate competence, compassion and caring.

Patients today are savvy healthcare consumers. They judge healthcare providers not only on clinical outcomes, but also on the courtesy of their personnel, the convenience of their facilities and their ability to deliver excellent service. My goal is to create a patient experience that distinguishes us from all other providers — an experience that gives patients complete confidence that Cleveland Clinic is the best choice for their care.

To show just how committed we are to improving the patient experience, I recently created the new position of Chief Experience Officer and appointed Bridget Duffy, M.D., to the post. Dr. Duffy comes to us with a national reputation in humanistic medicine. She will work with our leadership to create and sustain a culture in which everyone at every level of Cleveland Clinic feels ownership of, and responsibility for, patient satisfaction.

One of the more immediate changes patients will begin seeing is in our hospital gowns. Anyone who has ever been a patient understands how vulnerable and exposed the traditional hospital gown can make you feel. We decided that was no longer acceptable. In June, we unveiled a new hospital gown that preserves patient dignity and modesty, yet is fully functional from the caregivers' perspective. Patients have already told us that it is a vast improvement over the old one.

It is our duty to remember that empathy lies at the very heart of the healthcare profession. Remember the old family practitioners who, with black bag in hand, visited patients in their homes? Empathy was an important part of these doctors' practice. The healthcare they provided, however, was limited in its scope. Since that time, we have in many ways become technocrats — putting empathy on the back burner and focusing more on the development and delivery of superior treatments. Now, our job is to swing the pendulum back to the middle so we can strike the proper balance between empathetic care and quality medical outcomes.

In the end, patients who come to Cleveland Clinic will judge us on the experience they have. Whether it is a confident and healing experience is up to us.

Delos M. Cosgrove

# Taking Ankle Replacement in Stride

Two decades ago, Karl Morgenthaler was trimming a large willow tree in his backyard when a limb fell. It pushed him to the ground and trapped his foot between the branches. Mr. Morgenthaler knew instantly that his ankle was broken.

Surgery repaired the ankle and held it together with a metal plate and seven screws. Everything was fine — until arthritic deterioration caused bone to rub on bone.

CARY WOLINSKY/GETTY IMAGES

"I'm on my feet a lot," says Mr. Morgenthaler, who lives in the Cleveland suburbs and co-owns a manufacturing plant. "The pain was excruciating. Something had to be done."

Mr. Morgenthaler's options were limited. The standard surgery for his condition is fusion of the ankle joint, using bone to bridge the tibia, or shin bone, and the talus, one of the ankle's main bones.

But the ankle has a tough job to do, and flexibility is essential for balance and walking. Fusing the ankle reduces the joint's range of motion, causing the patient to walk with a limp.

"I wanted to be able to bend my ankle and walk normally," he says.

Artificial ankle joints didn't strike him as a substantially better option. In his research, Mr. Morgenthaler learned that metal ankle replacements, held in place with screws, often loosen over time and need repeat surgery. The lifespan of a typical ankle prosthesis is about 10 to 15 years.

Then Mr. Morgenthaler learned about a new prosthesis that became available in the United States in December 2006. It was developed with Brian Donley, M.D., Vice Chairman of Orthopedic Surgery at Cleveland Clinic.

"We designed the prosthesis with the goal of offering better natural movement and greater comfort with the active patient in mind," says Dr. Donley, who was the first surgeon in the United States to conduct the new replacement procedure. "Its design better replicates the natural anatomy of the patient's own ankle."

The replacement ankle's slim design means less of the patient's bone is removed. It also means a smaller incision for the procedure, leading to shorter recovery time.

How the device will perform in the long term is still being studied, but doctors expect that the prosthesis is less likely to loosen over time. It also gives the patient more options if surgery is needed again in the future, says Dr. Donley.

Mr. Morgenthaler had his surgery in March 2007. After a period of immobilization in a boot splint and gentle exercise, he's back to bearing weight on the ankle and walking pain-free. "I can do anything; rotate the ankle or bend it up and down," he says. "It feels great. It's getting stronger every day." — BRUCE GOLDFARB

# Rebuilding Hope After Mastectomy

Breast cancer patients who have had a mastectomy may be surprised to find they have options if they choose to have breast reconstruction surgery.

The most common and widely known reconstruction methods are breast implants and the transverse rectus abdominal muscle (TRAM) flap. The TRAM flap, which uses the patient's own tissue, requires a flap of abdominal muscle and tissue still attached to its blood supply to create the breast mound.

Both options can produce high-quality results, but patients have another choice.

The deep inferior epigastric perforator (DIEP) vessel flap procedure offers breasts that look and feel natural. They are constructed from the patient's own tissue without compromising her all-important "six pack" abdominal muscles. "DIEP has the benefit of preserving the shape and strength of the abdomen," says Cleveland Clinic plastic surgeon Risal Djohan, M.D.

With DIEP, a hip-to-hip incision is made in the lower abdomen to remove skin, fat and blood vessels. The tissue and skin are then transplanted and molded to create a natural-looking breast. Using delicate microsurgery techniques, the blood vessels from the transplanted tissue are connected to blood vessels in the area of the mastectomy using sutures finer than a strand of hair. The nipples and areolas are constructed later during a second surgery. DIEP's advantages can be significant, especially for physically active women.

"With the TRAM flap procedure," Dr. Djohan says, "there might be some impairment or weakening of the stomach muscles. There might be an increased risk of hernia."

For some patients, DIEP has an added benefit. Because the procedure doesn't require muscle to be taken from the abdomen — only fat — the surgery mimics a tummy tuck, even improving the abdominal contour.

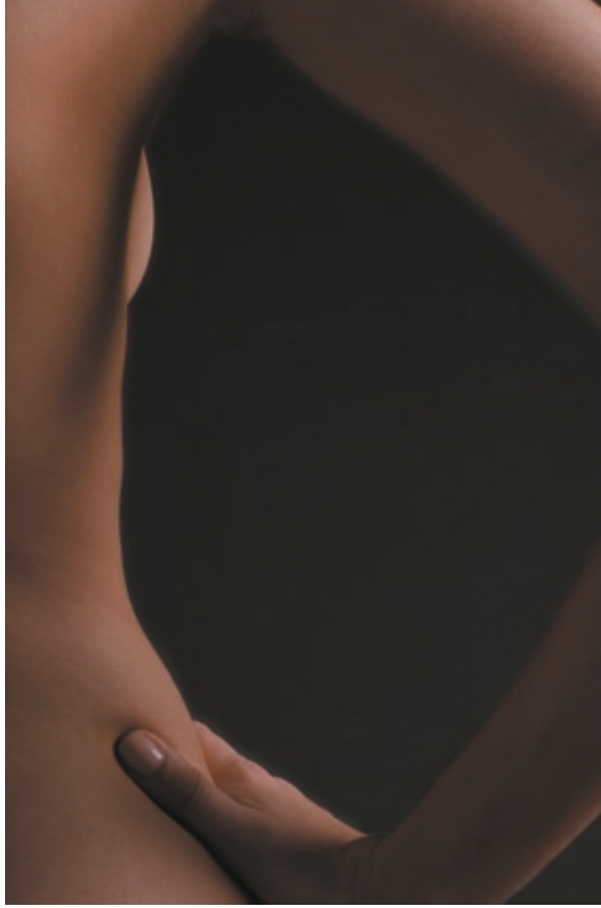
DIEP flap reconstruction isn't right for everyone, though.

Women who have too little fatty stomach tissue — as well as those who have too much — may not be candidates. And, while patients who have had Caesarean sections and other abdominal surgeries are typically eligible for DIEP, those who have had previous tummy tucks are not.

"Not everyone is able to do it. But if we're able to offer women another choice for breast reconstruction, that's a good thing," says Dr. Djohan. — TRICIA SCHELLENBACH

JAMES DARELL/GETTY IMAGES

View a video about this procedure at **clevelandclinic.org/ccm**.



## INSURING RECONSTRUCTION

Under federal law, health insurers that provide coverage for a mastectomy are generally required to also provide coverage for a related breast reconstruction. Fewer than 25 percent of breast cancer patients, however, pursue breast reconstruction. And the numbers drop significantly for African-American, Hispanic and Asian women. Reasons for not seeking reconstruction vary. Some are never referred to a plastic surgeon. Others are unwilling or unable to undergo more surgery. Still others cite time and cost constraints.

Breast reconstruction, however, is available as an insurance-covered procedure under the Women's Health and Cancer Rights Act of 1998. This act states that if a patient has health insurance that provides medical and surgical benefits related to a mastectomy, the carrier must also provide coverage for:

- Reconstruction of the breast on which the mastectomy was performed
- Surgery and reconstruction of the other breast to produce a symmetrical appearance
- Prosthetics and physical complications at all stages of the mastectomy

Patients should consult closely with their doctors and their insurance companies to determine their options.

# Picture This

A futuristic technology is opening a remarkable new window into a child's small intestine. It's allowing doctors to visualize the twists and turns between the stomach and large intestine, which is notoriously difficult to reach and navigate and has long been a challenge for physicians as they work to diagnose problems.

Traditionally, endoscopes — instruments that reveal the insides of hollow organs — have been the answer, but they have mobility limitations. Other diagnostic options, which rely on barium drinks and CT (computed tomography) scans, are a tough sell — especially with children — and the results may not be definitive.

A tool recently made available for use in children takes an entirely different approach. The technique, called capsule endoscopy, employs a tiny camera in the shape of a large pill that is swallowed. Inside the body, the camera snaps tens of thousands of color photographs while it travels the length of the gastrointestinal tract. The photographs are transmitted wirelessly to a receiver worn around the patient's waist and then downloaded to a computer for evaluation.

"Capsule endoscopy is a tool that allows us to make an earlier diagnosis and intervention than we otherwise would be able to," says Robert Wyllie, M.D., Physician-in-Chief of Cleveland Clinic Children's Hospital. "The result is that we're able to significantly reduce the time it takes to diagnose and treat intestinal disease. It's truly a remarkable breakthrough."

Dr. Wyllie and his team have used capsule endoscopy in children as young as 3 to diagnose Crohn's disease, celiac disease, tumors, vascular problems in the small intestine and malabsorption disorders. Cleveland Clinic began using this Food and Drug Administration–approved technology in 2002; since then, about 200 children and many more adults have undergone the process, says Dr. Wyllie.

Given Imaging Ltd., the Israeli company that manufactures the capsule endoscopic camera, worked closely with gastroenterologists at Cleveland Clinic to develop the device, dubbed the PillCam™. The PillCam is just over an inch long and a bit less than half an inch wide and provides a 140-degree field of vision as it moves through the intestine. Although most adults and older children can swallow the PillCam, smaller children typically require general anesthesia and insertion of the PillCam beyond the stomach using an endoscope.

Once activated, the camera snaps two images per second, or about 57,000 frames during a typical eight-hour journey through the body, as the patient goes about his or her normal day. To speed review of the images, sophisticated software sorts and flags pictures that may show anomalies or other problems.

"Someday, it may be possible to steer the device and monitor the camera in real time so that if you saw something, you could focus on it," Dr. Wyllie says. — BONAR MENNINGER

CHRIS WINDSOR/GETTY IMAGES

## Sealing Off Tangled Blood Vessels

In December 2006, U.S. Sen. Tim Johnson of South Dakota underwent emergency surgery for bleeding in his brain. The bleeding was caused by an arteriovenous malformation (AVM), a congenital defect that turns normal veins and arteries into a potentially lethal tangle of blood-filled vessels. Sen. Johnson is on the road to recovery, but AVMs, especially those in the brain, are very serious.

Many people never realize they have an AVM, but an estimated 300,000 Americans are affected. Only about 36,000 people experience symptoms, which include seizures, headaches, visual disturbances or stroke. Medication can alleviate some of these issues, but AVM treatment often includes surgery to remove the tangled vessels.

A new material called Onyx is making AVM surgery less risky. Onyx is a liquid that is injected with special micro-catheters directly into the AVM, where it hardens and cuts off blood flow. "Onyx reduces the amount of bleeding during surgery," explains Peter Rasmussen, M.D., Head of Cleveland Clinic's Cerebrovascular Center. "It allows us to isolate the AVM more effectively and remove it completely. Without prior treatment with Onyx, bleeding can get in the way and reduce our ability to dissect around the AVM."

Sealing off the AVM can prevent the arteries and vessels from rupturing during surgery. It may also reduce hemorrhaging during recovery.

Used in Europe for a decade, Onyx was approved for use in the United States in June 2005. — NICK KOLAKOWSKI





# A Man of Influence

Steven Nissen, M.D., reflects on activism and being named one of *TIME* magazine's 100 most influential people

Steven Nissen, M.D., is perhaps the world's leading drug-safety advocate. In 2001, he was one of the first physicians to link the pain-killer Vioxx® to an increased risk of heart attack and stroke. This year, he made headlines raising questions about the diabetes drug Avandia®. Pharmaceutical companies are listening to Dr. Nissen. A closer look at Cleveland Clinic's Chairman of Cardiovascular Medicine helps explain why.

▶When did you become an activist? I really started in college. I was in college in the late 1960s, during the Vietnam War, during the civil rights movement. I very quickly embraced those causes, and that activism has stayed with me.

▶And it's made you influential. What does that mean to you? If you are a person who is influential, well then, it's incumbent upon you to use that influence to, hopefully, benefit society.

▶You started benefiting people's health at a very young age, didn't you? Ha! Well, in 1962, I was then 14 years old, the Surgeon General's report, *Smoking and Health*, was first issued and a copy was sent to every physician in the United States, and my father is an obstetrician/gynecologist. Of course, I immediately picked it up and started reading it. And it was very clear that smoking was very bad — heart disease, cancer — so my father, who was a smoker at the time, came home and I confronted him with the science. He quit on the spot.

▶One of the reasons you've remained empowered as a drug-safety advocate is that you avoid conflict-of-interest issues. You don't take compensation from pharmaceutical companies. Was that a hard decision to make? It was a very pivotal decision. I felt very uncomfortable receiving compensation because, really, I do need to be independent. So it was not an easy thing to do, but it was certainly the right thing.

▶How do you balance your public and your private life? I occasionally will get on a bicycle with my wife [photographer Linda Butler]. I tend to be pretty focused and sometimes a bit one-dimensional, but, you know, I really love what I do.

▶Are you proud of the recognition you received this May from *TIME*? I'm still very surprised by it. I still can't quite believe it. I accept this, but I really accept it in many ways as a representative of the Clinic and of the department. I happen, as Chair of the department, to be the one being honored, but it's the team. It's about the team.

▶Where do you think your research will take you? I'm really very hopeful that in the next five to 10 years, we can offer patients something more than just slowing the inexorable progress of fatal coronary disease. To actually reverse the disease, that's clearly a central passion of the work we're trying to do.

YU KWAN LEE

To view a video interview of Dr. Nissen, visit **clevelandclinic.org/ccm**.

# Taste Every Bite

**Imagine you are eating a Hershey's Kiss.** Before you start to eat it, hold it in your hand. Look at the outside. As you open it, listen to the crinkle of the foil. Bring it up to your nose and deeply inhale a few whiffs of the chocolate. Put it in your mouth and roll it around on your tongue. Try to think about any feelings or thoughts that come to mind.

Welcome to Chocolate Meditation, a way of eating that encourages people to savor every bite and end what some call "mindless eating."

About 127 million U.S. adults are overweight or obese, according to the American Obesity Association. Many of these cases of overeating could be resolved if people thought about what — and how much — they ate, argues Susan Albers, Psy.D., a Cleveland Clinic psychologist and author of *Eating Mindfully: How to End Mindless Eating and Enjoy a Balanced Relationship with Food*.

"Eating is like tying your shoe or brushing your teeth," says Dr. Albers. "You just do it in a very automatic or routine way. But when you're doing this, you aren't thinking much about what you're eating. You might get to the bottom of a bag of chips and realize you didn't taste one single bite. And that's when you go for more."

• • •

**OUT WITH THE FAD** Trendy diets and other weight-loss fads tend to be short-term solutions that don't provide a conscious, realistic change in eating habits, says Dr. Albers, who counsels patients individually and in group workshops on dietary issues. Eliminating entire food groups or completely denying yourself favorite treats can lead to trouble later on, she warns.

"Anything you take away, you start to crave," says Dr. Albers. "It's impossible to cut out everything."

With Chocolate Meditation, no food is off limits. Dr. Albers, who has lectured widely on the topic across the country, encourages people to be aware of how much, and why, they eat. And although she realizes it may not be practical for every meal, she says this mindfulness still pushes people to think differently about what goes into their mouths.

"I don't tell people to get rid of chocolate," says Dr. Albers. "It's not realistic, and what fun would life be if you got rid of chocolate? You just need to eat it, or whatever your food of choice may be, in a mindful way."

• • •

**STEP BY STEP** Eating mindfully is based on four foundations: mind, body, feelings and thoughts. Before taking a bite, Dr. Albers suggests, people should ask themselves how hungry they are on a scale of one to 10. By constantly checking in with themselves, people can develop a better sense of what their bodies are feeling, she says.

Sometimes these clues are subtle. For example, a person might think they have no energy or are very stressed when they're just hungry. "It's really about tuning in to your body and about what your body is telling you," says Dr. Albers.

Feelings and thoughts also can have a significant impact on how much people eat. For some, these emotions can be positive. For others, eating may be fueled by anxiety, guilt, stress or just boredom.

"The first thing I help people target is rewriting those negative scripts in their head," explains Dr. Albers. "Just being more mindful of their internal speech affects a lot of what they eat."

In addition to keeping a healthy eating script in mind, avoid multitasking when eating, she suggests.

"When you eat, just eat. When you're watching TV and eating, or driving and eating, that's when your body doesn't register just how much you're having." Also, put food out of sight and make it less accessible, which will discourage the mindless grab-and-eat habit.

"Everybody, no matter where you are in the spectrum of eating, can learn to eat more mindfully," says Dr. Albers. "This is a long-term approach." — MEREDITH STANTON

To read an excerpt from Susan Albers' book, *Eating Mindfully,* or to listen to a podcast by Dr. Albers, go to **clevelandclinic.org/ccm**.

RONALD RAMMELKAMP/JUPITER IMAGES

# Patient in a Pinch

**Eduardo Perez* is a busy businessman** who, in his free time, relishes precious moments spent driving his sports car through the lush countryside near his home outside San Juan, Puerto Rico. Mr. Perez, 65, enjoys living in the fast lane and had never let life's little speed bumps slow him down.

Then he hit a roadblock.

Persistent pain in his neck and arms had troubled Mr. Perez for several years. Finally, he sought treatment from an orthopedic surgeon regarded as one of the best in Puerto Rico. X-ray images indicated spondylosis, an arthritic degeneration of bone and cartilage in the vertebrae of the neck.

With spondylosis, also known as spinal osteoarthritis, the spinal canal may be narrowed. Arthritic bone can compress the spinal cord and nerves, and bone spurs inflame adjacent tissues. Spondylosis can cause severe pain of the neck, arms, shoulders, back and legs. People with the condition may also have headache, numbness, weakness, muscle spasm, loss of balance and other neurological symptoms.

The surgeon recommended a laminectomy, a surgical procedure to relieve pressure on the spinal cord and nerves. After Mr. Perez's laminectomy was performed in 2001, his symptoms improved — for a while. And then neurological problems returned with a vengeance. In the years following his surgery, Mr. Perez developed a progressive myelopathy, which is a spinal cord disorder. He experienced weakness and loss of sensation in his arms and legs. He felt pins and needles in his fingers and had problems holding cutlery or writing with a pen. He had increasing difficulty walking and soon started using a cane. Mr. Perez realized there was a serious problem when he felt unable to move his foot from the accelerator to the brake pedal while driving his Porsche 911 — a powerful vehicle that demands full control.

The orthopedic surgeon in Puerto Rico, stumped by his patient's symptoms, referred Mr. Perez to Cleveland Clinic for an evaluation.

**The patient's name and other details have been changed to protect his privacy.*

◀ This magnetic resonance image (MRI) shows Eduardo Perez's spinal cord traveling down the vertebral column.

## THE OFFICE VISIT

Surgeon Edward Benzel, M.D., of the Center for Spine Health, looked at the X-ray Mr. Perez brought with him from Puerto Rico. The image showed a spinal cord that was noticeably atrophied, or shrunken. There were no defects, deformities or visible cause of the symptoms. "This doesn't make sense," Dr. Benzel told his patient.

Dr. Benzel consulted neurologist Cathy Sila, M.D., of Cleveland Clinic's Cerebrovascular Center. She agreed that something must be causing the spinal cord atrophy and the patient's symptoms. "His spine X-rays, however, didn't show any compressive cause of his ongoing neurological problem. What else could it be?" she asked. The answer, for the moment, remained a mystery.

Ever the gentleman, Mr. Perez struggled to his feet to greet Dr. Sila in the exam room. She performed a thorough neurological assessment, starting at the top of the head and working down the body. She tested each of Mr. Perez's muscle groups, checking for strength and symmetry, and she mapped out the sensation of Mr. Perez's skin. She assessed reflexes and evaluated the patient's balance and gait.

"It's a lot like taking the back off a television set, testing all the circuits to find the burned-out tube," says Dr. Sila.

The neurological deficit appeared to begin at the level of the neck and shoulders. Was this a worsening spondylotic myelopathy, or was a chronic neurological disease the culprit? As she evaluated her patient, Dr. Sila began to formulate a list of likely causes:

**MULTIPLE SCLEROSIS** Multiple sclerosis (MS) is a chronic inflammatory disease affecting neurons of the central nervous system. The myelin sheath that protects neurons is attacked by the immune system, leaving multiple areas of scar tissue, or sclerosis. MS most often develops in people 20 to 40 years of age, although it can occur at any age.

**AMYOTROPHIC LATERAL SCLEROSIS** Often called Lou Gehrig's disease, amyotrophic lateral sclerosis (ALS) is a progressive and invariably fatal disorder that attacks neurons responsible for controlling voluntary muscles. People with the disease lose the ability to move their arms and legs, along with other muscles of the body, as neurons die. Eventually, the disease affects the diaphragm and other muscles of the chest, and the patient is unable to breathe without a ventilator.

**VITAMIN B-12 DEFICIENCY** Vitamin B-12, also known as cobalamin, is essential for the normal function of red blood cells and nerve cells. Deficiency of vitamin B-12 can result in anemia and nerve damage. People with vitamin B-12 deficiency may have tingling and loss of sensation, muscle weakness and impaired mental functioning. The legs are usually affected before the arms.

**CERVICAL SPONDYLOTIC MYELOPATHY** Cervical spondylotic myelopathy, the most common cause of spinal dysfunction in older adults, results when the spinal cord is pinched by bony spurs and discs that result from degenerative changes in the discs and facet joints. Symptoms include neck stiffness, arm pain, and numbness and weakness of the extremities.

## MAKING THE DIAGNOSIS

Dr. Sila studied her neurological assessment. Dr. Benzel, meanwhile, noticed that his patient had exceptional flexibility in his neck, likely a result of his laminectomy years ago. Based on those observations, Dr. Benzel ordered magnetic resonance imaging (MRI) of Mr. Perez's neck. He hoped the MRI could give him a clearer picture of what was causing his patient's pain. — BRUCE GOLDFARB

Get the final diagnosis at **clevelandclinic.org/ccm**.

## TAKE OUR ONLINE POLL

### Should the HPV vaccine be mandatory?

In June 2006, the Food and Drug Administration approved the human papillomavirus (HPV) vaccine described in this issue's article about medical innovations (page 26). The vaccine has the potential to prevent cervical cancer caused by certain strains of the sexually transmitted virus. As excitement surrounding the vaccine has grown, some states, cities and even school districts have taken steps toward requiring girls to be vaccinated, often around middle-school age.

Supporters of these mandates say the potential life-saving benefits of the vaccine are too great to ignore. Opponents argue the vaccine would encourage risky sexual behavior and that the vaccine's effectiveness is still unclear.

We want to know what you think. Should the HPV vaccine be required?

**ALSO ON THE WEB** [clevelandclinic.org/ccm]

### Results from last issue's poll

**Readers speak out on healthcare pricing**

In our last issue, we asked readers to share their thoughts on the importance of pricing in their healthcare decisions. Here's what you had to say:

> **"When it comes to the health of my family, quality matters more than cost. Health decisions shouldn't be based on low-bid contracting."**

> **"Healthcare should be treated like any other commodity in our capitalism-driven economy. We can shop around for cars, houses and clothes, so why not healthcare?"**

63% Yes, pricing is an important factor in deciding where I should go for healthcare.

28% No, pricing isn't really an important consideration in my healthcare choices.

9% I'm not sure whether costs factor into my healthcare decisions.

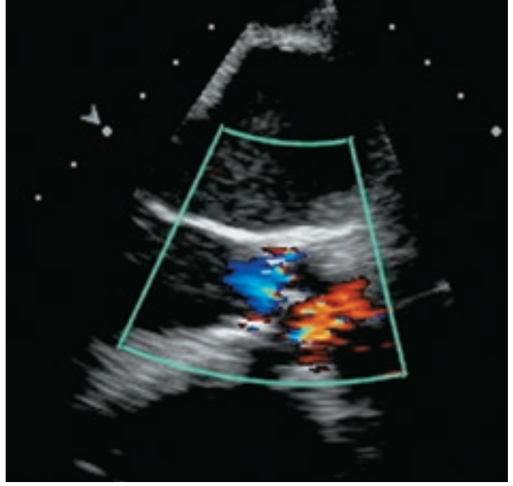
# mending broken hearts

## New research makes aortic valve replacement possible — even for frail, older patients

BY CORI VANCHIERI AND JOSH FISCHMAN • ILLUSTRATION BY BRYAN CHRISTIE

Everett Hoover was missing out on life's simple pleasures. He used to be a gardener, but no more. He longed to visit his daughter, but the trip from Kent, Ohio, to the Florida Keys was too much for him. Just walking across the room left him out of breath.

The 80-year-old great-grandfather of six was told that his aortic valve was giving out and that he was too old and weak for standard surgery to replace it. He wasn't ready to give up, though. His doctor told him about an experimental procedure that would replace the valve without putting too much stress on his body. Mr. Hoover didn't hesitate. "I said, 'Go for it,'" he recalls.



A post-implantation echocardiogram of a replaced aortic valve allows doctors to view their work. Echocardiography uses sound waves to create a moving picture of the heart. It can reveal whether the new valve has been positioned correctly.

In a special operating room at Cleveland Clinic, images of one of the most delicate yet powerful parts of the body flicker on monitors surrounding a surgical table. The aortic valve, made of three leaflets of tissue that open and close like a flower's petals with every beat of the heart, is pulsing. This tiny structure, about an inch across in an adult — or as wide as a quarter — sits at the junction of the heart's main pumping chamber and the body's biggest blood vessel. It controls the flow of oxygen-rich blood to every vital organ of the body.

The valve in this scene, however, is barely opening. Shown on six fluoroscope monitors that provide moving X-ray pictures of the valve from every angle, the three leaflets are stiff with calcium deposited over many years. The opening to the aorta has narrowed to the width of a straw, letting only a trickle of blood come through. It is a slow sentence of death.

Cleveland Clinic cardiac surgeons and cardiologists are going to replace the failing aortic valve with a new one — without the need for open-heart surgery. Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., and Samir Kapadia, M.D., work together to insert the new valve through one of two remote locations in the body. In one approach, a long, flexible tube called a catheter is fed through an artery in the groin. In the second approach, the catheter goes in through a small chest incision.

At the end of the catheter sits the replacement valve: three leaflets made of supple, sterilized cow tissue surrounded by a metal mesh cage. The team guides the new valve through the narrow opening into the aorta and inflates a balloon to crack the calcium that has gathered on the old, stiff valve. It then pushes it apart. The mesh cage holds the old valve open while the new one begins fluttering in the freshly widened channel, opening and closing as the heart expands and contracts.

"We call this procedure percutaneous aortic valve replacement (PAVR) because the replacement valve is slipped into place through an artery just under the skin," says Dr. Tuzcu. "It may offer an option to very sick patients who could not withstand open-heart surgery or even minimally invasive surgery."

Cleveland Clinic's Heart and Vascular Institute is one of three places in the nation evaluating PAVR. This spring, the Food and Drug Administration (FDA) allowed the research study to move from testing in just a few dozen patients to a randomized study involving 600 patients. Doctors will compare the effectiveness of PAVR — this time threading a catheter through the femoral artery in the groin all the way to the heart — against standard-care procedures.

About 200,000 people around the world need aortic valve repair, according to the European Society of Cardiology. A third or more never get treated because until now, valve surgery had to be done by cutting into the heart and putting the patient on a heart-lung bypass machine. Advanced age or other illnesses made that much too risky. "When aortic valve narrowing is causing symptoms, people in this condition have a 30 percent to 50 percent chance of dying within a year," Dr. Tuzcu says. "You have to replace that valve."

PAVR techniques are bringing new hope to people like Mr. Hoover, whose valve was replaced by Drs. Kapadia, Svensson and Tuzcu through a small incision in his chest. The retired builder had been an avid woodworker who enjoyed working on his yard. "He'd do anything for the kids," says Shirley, his wife of 57 years. "If they wanted a bookcase, he'd give it a whirl." But last fall, the man who had built the home his three children grew up in could do almost nothing that required effort or strain. His aortic valve was severely and dangerously narrowed.

The aortic valve is a stress point unlike any other in the body. Located between the powerful left ventricle of the heart — the main pumping chamber — and the high-pressure trunk of the aorta, the valve sustains the greatest forces in the circulatory system. And as people age, the valve can fail. Calcium carried by the blood is deposited on the valve leaflets, narrowing the opening, in a condition called aortic stenosis. It affects 2 percent to 3 percent of people over the age of 75.

Medication can help up to a point. Doctors can prescribe diuretics and beta blockers to reduce the blood volume in circulation and control blood pressure, all to ease the burden on the heart. But as the valve continues to deteriorate, the heart loses the ability to compensate and slides into heart failure, unable to force enough blood into the aorta to keep the body going. Dr. Svensson says the drugs are really a means of preparing the patient to be in the best shape for surgery. "If patients come early to surgery





Last fall, the man who had built the home his three children grew up in could do almost nothing that required effort or strain.

Everett and Shirley Hoover

STEPHEN TRAVARCA

and don't have a badly weakened heart, they can expect a full recovery and normal life expectancy," says the cardiac surgeon. If the heart is already badly weakened, the patient will remain on drugs after the surgery.

The severity of aortic valve disease is described using two grading systems. One system describes a leaking valve as mild, moderate or severe on a scale of zero to four, with four being severe. Aortic valve stenosis, the narrowing of the valve, is graded based on the size of the opening in the valve. A normal valve is more than 3 square centimeters wide. Mild stenosis is about 1.5 to 2 square centimeters, moderate ranges from 1 to 1.5 square centimeters, and severe shrinks below 1 square centimeter, the narrow straw opening, says Dr. Svensson.

For severe disease, the gold-standard treatment has been open-heart surgery. Here, the chest is opened from just below the Adam's apple to just above the belly button. The heart is forced to stop beating while blood is pumped through a heart-lung bypass machine, where oxygen is added, and then sent back into the aorta, where it travels to the rest of the body. The diseased valve is excised by the surgeon and replaced either with a mechanical device, a valve from a pig or a valve constructed from a cow's heart sac, or pericardium. Open-heart surgery is a major procedure that involves an extended stay in the hospital and weeks to months of recuperation.

Today, minimally invasive surgery, using a much smaller incision in the chest, is the norm. As a result, infection and complication rates are lower and the recovery time is much shorter. A keyhole approach is used, with a 3-inch incision, but the patient still goes on the heart-lung bypass machine. About 95 percent of the first-time heart valve surgeries performed at Cleveland Clinic today are minimally invasive with less than a 1 percent risk of death.

"When aortic valve narrowing is causing symptoms, people in this condition have a 30 percent to 50 percent chance of dying within a year. You have to replace that valve." — E. Murat Tuzcu, M.D.

The replacement valve's metal mesh cage surrounds three leaflets of sterilized cow tissue.

## UNDERSTANDING THE TERMINOLOGY

**Aortic valve:** The valve located where the aorta — the main artery carrying blood away from the heart — meets the heart's left ventricle. It allows blood to flow from the heart to the aorta and prevents backflow.

**Bicuspid aortic valve:** A valve that has only two cusps, or leaflets. A normal aortic valve has three leaflets. Later in life, a bicuspid valve may become calcified, resulting in narrowing or leakage. Leaking valves can usually be repaired.

**Calcification:** A condition in which the movement of a valve is limited by mineral deposits and wear.

**Catheter:** A hollow, usually flexible tube that is inserted into the body, often to deliver or remove liquids or medical devices.

**Heart-lung bypass machine:** A pump used to maintain circulation during heart surgery. It diverts blood from the heart, oxygenates it and pumps it through the body.

**Minimally invasive:** A procedure that is carried out by entering the body through natural openings or small incisions with the least amount of damage possible. Advantages include less pain and faster recovery.

**Percutaneous:** Performed through a small opening in the skin.

**Stenosis:** A narrowing that prevents the aortic valve from opening properly.

**Stent:** A small wire mesh tube that acts as a scaffold to provide support inside an artery.

These surgeries are not minimal enough, however, for Mr. Hoover and other elderly patients like him. In Mr. Hoover's case, years inhaling sawdust as a builder had wreaked havoc on his lungs. He had a severe case of chronic obstructive pulmonary disease, which hampers normal breathing. He'd already been hospitalized several times with pneumonia brought on by his lung disease. And now his aortic valve, hampered by severe calcium buildup, was functioning at about 15 percent capacity.

During a dire breathing episode in October 2006, he was transported to Cleveland Clinic for a valvuloplasty, which is when a balloon is inserted by catheter into the aortic valve to open it up. The procedure improved his breathing and showed that the valve was a major contributor to his breathing problems. The balloon, however, was not a long-term fix.

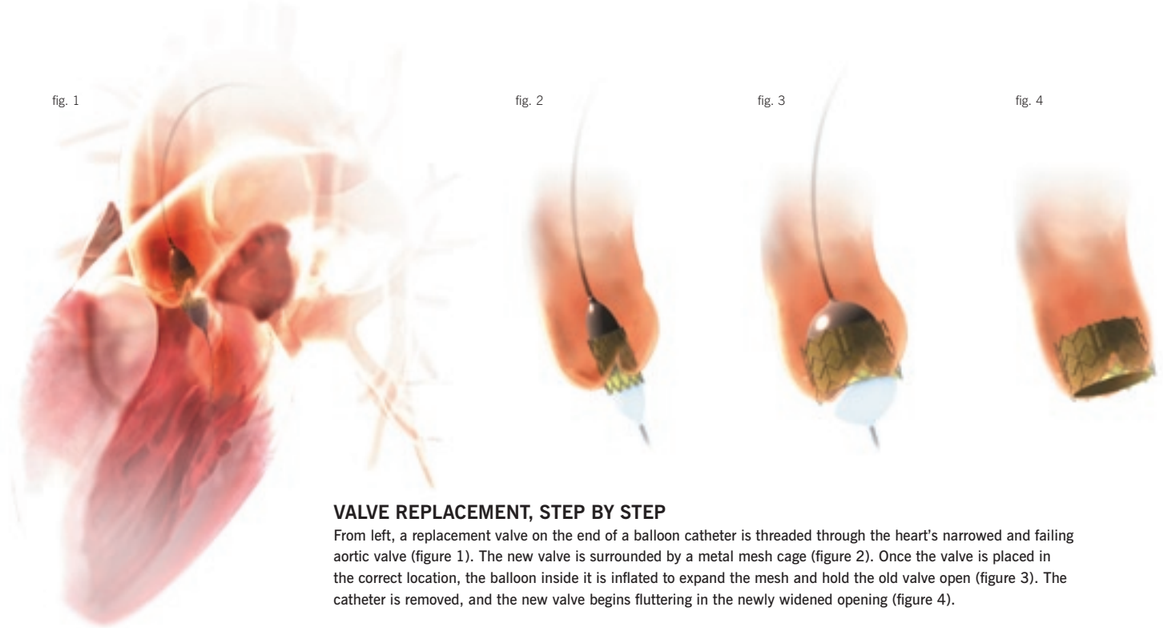
Mr. Hoover needed a new valve, but open-heart surgery, even minimally invasive surgery, was out of the question. Even without additional medical problems complicating his case, Mr. Hoover's age made him a poor candidate for surgery. The risk of complications was too high.

But in May 2006, Cleveland Clinic doctors launched a clinical trial to test a catheter-installed experimental device called the Cribier-Edwards percutaneous valve. To participate in the clinical study, the patient had to be more than 70 years old and meet other clinical criteria for high-risk surgery. Because inserting the catheter does not require opening the chest and no heart-lung bypass machine is needed, the procedure is even less invasive than minimally invasive surgery. They began the study with the hope that it might be a new option for the sickest, most elderly patients.

The Cribier-Edwards valve has leaflets made from the pericardium of a cow. Pericardium is tough but flexible tissue that can withstand the rigors of the circulatory system. The valve is attached to a stainless-steel mesh stent that surrounds it like a basket, holding it in place over the diseased aortic valve without the need for sutures. Once in the correct location, a balloon is used to expand the mesh, which becomes anchored in the calcium of the old valve's leaflets. The valve is also being evaluated at New York Presbyterian/Columbia University Medical Center in New York City.

One other percutaneous valve, called the CoreValve, is not yet available for testing in the United States. It consists of a three-leaflet valve made from pig tissue inside a three-part self-expanding metal frame, and can be introduced on a smaller catheter. "That has its pros and cons, because the smaller the catheter gets, the less control you have," explains Dr. Svensson. "But we want to look at all options. It may become available for study in the U.S. in the middle of this year."

RICHARD LAM/AP IMAGES




**VALVE REPLACEMENT, STEP BY STEP**

From left, a replacement valve on the end of a balloon catheter is threaded through the heart's narrowed and failing aortic valve (figure 1). The new valve is surrounded by a metal mesh cage (figure 2). Once the valve is placed in the correct location, the balloon inside it is inflated to expand the mesh and hold the old valve open (figure 3). The catheter is removed, and the new valve begins fluttering in the newly widened opening (figure 4).

Performing the PAVR procedure calls for a team of 35 health professionals working together in a highly coordinated fashion. "We're a bit like an orchestra," says Dr. Svensson. "We each step up and do our part." Experts in anesthesiology, echocardiology, radiology, cardiology and cardiac surgery are joined by two teams of circulating nurses — one intimately familiar with the operating room and the other expert in what happens in the catheterization laboratory.

The operating room is called a hybrid because it is set up for a full heart operation, if necessary. A team that handles the heart-lung bypass machine is in the room, at the ready, in case the patient needs bypass support. Multiple monitors let the medical staff see everything going on with the patient. One bank of monitors offers fluoroscopy images — continuous X-rays of the arteries and heart in motion — providing views of every angle of the path the catheter travels, plus the aortic valve itself.

Another group of monitors offers additional input, using echocardiography, or sound waves, to create a moving picture of the heart and offers a secondary way to make sure everything is positioned correctly. A third set of monitors tracks blood flow and measures blood pressure and oxygen in the blood.

Researchers are still refining the procedure and the design of the valve. "The first valve we used was too small, and so blood leaked around it, keeping it from doing an efficient job," says Dr. Svensson. "We've worked with the company to modify it and make it slightly larger and now there is less leakage."

In the first feasibility research study at Cleveland Clinic, inserting the catheter through the femoral artery in the groin, the procedure was tested in 55 patients. That study was completed in 2006. A second feasibility research study, completed in April, tested a small incision in the chest, known as a transapical approach, in 20 patients in whom groin access was not viable.

"About 80 percent of patients who received the valve are alive six months after the procedure," says Dr. Tuzcu, co-principal investigator for the project with Dr. Svensson.

The team is excited to begin the new, larger randomized trial of the device. "We've shown we can safely do the procedure in high-risk patients; now we can evaluate whether it is effective compared with standard techniques," Dr. Kapadia says. Six hundred patients will be enrolled at Cleveland Clinic, New York Presbyterian/Columbia University Medical Center in New York City, and other centers.

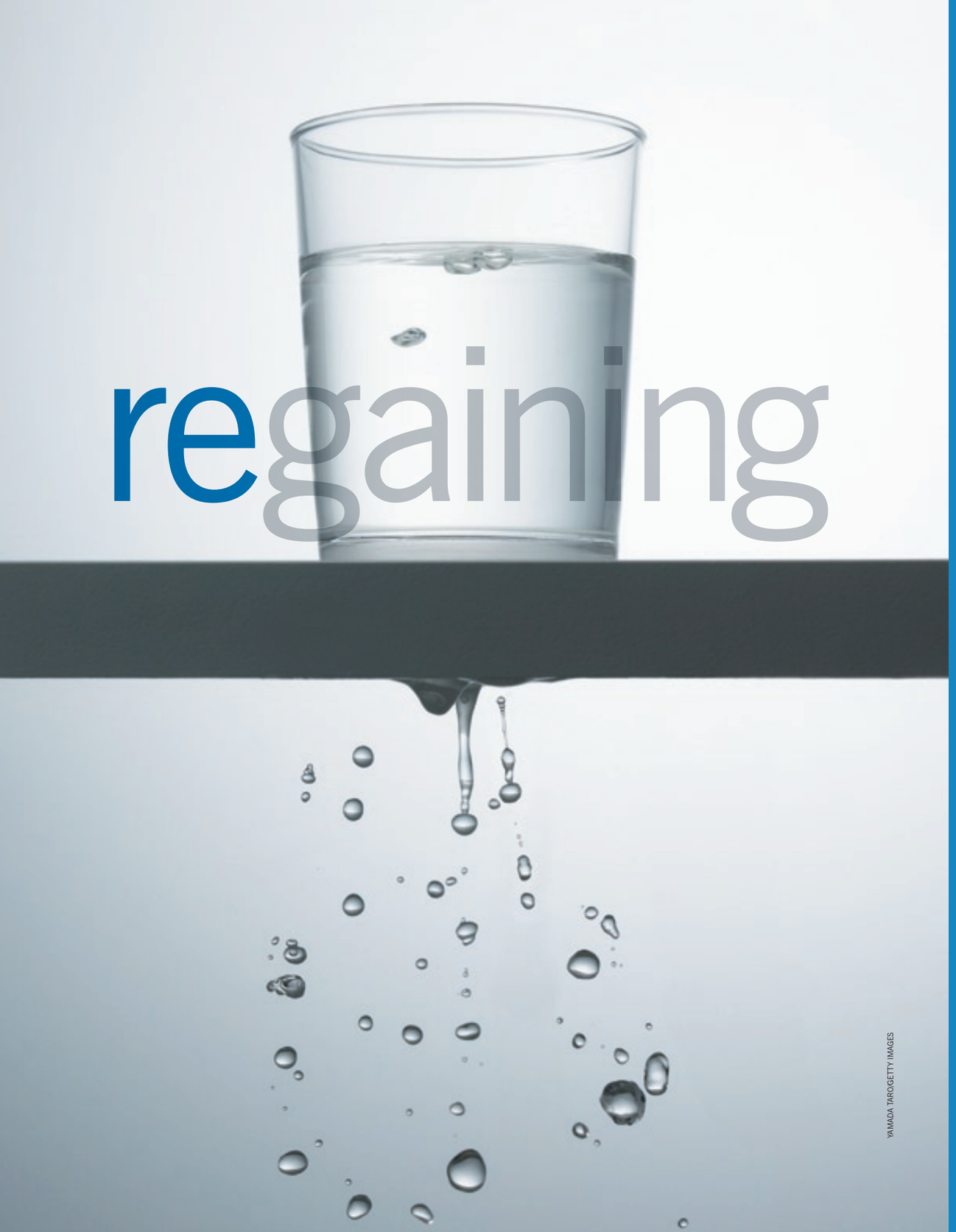
If development of the valve and procedure stays on track, the technique may become available to larger numbers of patients who would traditionally be considered too frail for open-heart surgery.

Mr. Hoover received his new valve in March 2007, and his breathing improved immediately. He is once again enjoying the things that give him pleasure. "I can run out to the screened porch and spend some time, tend my five tomato plants on the patio, all without the oxygen tank," he says.

His wife, Shirley, adds, "This gave him his life back. We haven't been able to go to Florida to visit our daughter, grandchildren, and great-grandchildren in three years, and we're hoping to do that soon."

BRYAN CHRISTIE

**Cori Vanchieri** is the former editor of Howard Hughes Medical Institute's *Bulletin* magazine and the former news editor of the *Annals of Internal Medicine*. **Josh Fischman** is the former senior healthcare editor of *U.S.News & World Report*. **Bruce Goldfarb** also contributed to this article.



YAMADA TAROIGETTY IMAGES

# regaining control

## IMPROVED SURGICAL TECHNIQUES OFFER PATIENTS NEWFOUND FREEDOM FROM URINARY INCONTINENCE

BY BRUCE GOLDFARB

Mari Madden dreaded funny jokes. Laughing, coughing, sneezing — anything that tickled her stomach or put pressure on her bladder — carried the risk of an involuntary urinary leak. “It was embarrassing,” says the 45-year-old nurse, who works at Cleveland Clinic. “I was constantly aware of it.”

Problems controlling her bladder began after the first of her two sons was born 18 years ago. “It pretty much started right afterward and never went away,” she recalls. “It seemed to get worse.” Wearing an absorbent pad under her clothing helped, but the fear of embarrassment was never far from her mind.

"As a nurse, I knew that surgery was out there, but I always thought it was for old people."

— patient Mari Madden

For Ms. Madden, who had been active in a variety of sports since youth, anything involving jumping, running or bouncing became out of the question. "I couldn't exercise much and couldn't run at all because of the risk of leaking," she says. As her activity level fell, her weight slowly increased, making her feel even worse.

"I didn't know that something could be done," she says. "As a nurse, I knew that surgery was out there, but I always thought it was for old people."

Ms. Madden is one of 13 million Americans with loss of bladder control, also known as urinary incontinence. The disorder is much more than an embarrassing annoyance. Urinary incontinence damages confidence and self-esteem and can lead to depression.

Although the problem affects millions, urinary incontinence is rarely discussed — even during visits with a doctor. "Most patients think incontinence is just a fact of aging or that they can deal with it because 'it's normal,' but it clearly is not normal," says Sandip Vasavada, M.D., a urologic surgeon and Co-Head of Female Urology and Voiding Dysfunction at Cleveland Clinic Glickman Urological and Kidney Institute. "It can be treated in most cases and doesn't always require surgery. Advances in recent years have minimized the invasiveness of therapy and led to many successes."

Today, many patients find relief in noninvasive treatments such as behavioral therapy, physical therapy and medication. Doctors can inject substances to augment and strengthen weakened sphincter muscles — and researchers are even exploring stem cell therapy to actually rebuild muscle tissue.

For patients in whom these techniques are ineffective, minimally invasive or outpatient surgery becomes the next step.

Ms. Madden had the most common form of urinary incontinence — stress incontinence. The sphincter muscles, doughnut-shaped muscles that serve as valves at the outlet of the bladder, become weakened, allowing urine to leak out when a person coughs, laughs, sneezes or engages in some activity that puts pressure on the bladder.

Surgical procedures to repair stress incontinence were once complex operations requiring a lengthy hospital stay and a prolonged, uncomfortable recovery. They are now done on an outpatient basis, using minimally invasive techniques that are less risky and painful.

Ms. Madden found relief with one of the latest surgical innovations for women with stress incontinence: a synthetic mesh sling designed to cradle and support a sagging urethra so it can remain closed when the bladder is under pressure without an accidental leak of urine. In what is known as a vaginal tape procedure, the mesh is placed through tiny incisions in the lower abdomen and vaginal wall.

The mesh sling "has gained acceptance as the leading technology for treating female incontinence," says Raymond R. Rackley, M.D., Co-Head of Female Urology and Voiding Dysfunction.

The mesh sling is a considerable improvement over older surgical techniques, which typically involved making incisions in the lower abdomen that meant several days in the hospital and weeks of recovery. "Everything we're doing now is much less invasive," says Dr. Vasavada.

During the surgery, a strip of synthetic polypropylene mesh about a half-inch wide is slipped through a small incision and positioned like a hammock beneath the urethra.

STEPHEN TRAVARCA

The synthetic polypropylene material is designed to encourage the patient's tissues to incorporate into it, anchoring the sling. No sutures are needed to hold the mesh. When the procedure is completed, the sling supports the urethra in its normal position.

The mesh sling procedure takes about an hour to perform, and after two hours in the recovery room, the patient can go home. The vaginal tape procedure has a high success rate, with about 90 percent of patients reporting complete resolution of their incontinence, Dr. Vasavada says.

Since her mesh sling surgery in 2002, Ms. Madden and her husband have resumed running — even competing in two half-marathons. The weight is dropping off, and the family is involved in recreational activities together. "I can go running, skiing, whatever I want," she says. "And I don't have to worry about it."

The mesh sling "has gained acceptance as the leading technology treating female incontinence."

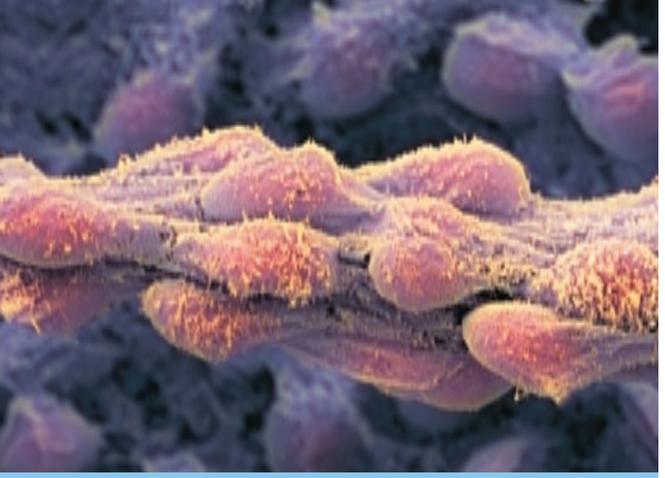
— Raymond R. Rackley, M.D.

## Preventing Incontinence Step by Step

**Although incontinence becomes more common with age, it is not considered a normal part of aging.**

**Women experience incontinence about twice as often as men.** The disorder may be caused by weakening of the muscles or other dysfunction of the structures supporting the urinary tract. Obesity and childbirth are common risk factors for stress incontinence. Other causes include infection, drug side effects, complications from surgery and diseases such as stroke, diabetes, multiple sclerosis and Parkinson's.

**A March 2007 report suggests that physical activity,** as simple as walking, reduces incontinence risk in women, especially stress incontinence. The data are from the Nurses' Health Study, a long-term study of nurses ages 54 to 79. The most active women were 15 percent to 20 percent less likely to report leaking urine than the least active women. Women who reported the most walking — the most common type of physical activity among the women — had a 26 percent lower risk of urinary incontinence than those who walked the least.



## The Stem Cell Solution

**Stem cells — those immature cells that have not yet developed into their specialized, mature form — may hold a futuristic solution to the age-old problem of incontinence.**

The key lies in regenerative medicine, which makes use of a patient's own stem cells to grow new tissue — in this case, new sphincter muscle tissue.

Raymond R. Rackley, M.D., at Cleveland Clinic Glickman Urological and Kidney Institute, sees great promise in this evolving therapy. "We can coax muscle cells to repopulate the sphincter by direct injection or by injecting medicines that provide the signals for stem cells present in the body to 'home' to the site of injury and dysfunction. Replacement of these cells creates improved sphincter function and may eliminate the need for reconstructive surgery."

Unlike other experimental therapies that use controversial fetal or embryonic tissue, the stem cells used to treat stress incontinence are adult stem cells that come from the patient or from a tissue bank. Here's how it works: Stem cells are obtained from the patient during a muscle biopsy. In the laboratory, stem cells can be coddled to mature and turn into specialized tissue. This new tissue is then injected into the patient's sphincter muscle during an office or clinic visit.

Clinical trials using stem cells to treat stress incontinence have been conducted in several centers in Europe and in Canada, with promising results. A 2006 report at the American Urological Association showed that, of 130 patients who received the therapy in an Austrian study, 111 experienced complete relief of their incontinence and 17 had partial relief.

Dr. Rackley and his colleagues are planning to test adult stem cells in patients with incontinence at Cleveland Clinic, and a clinical trial protocol is under development.

Ms. Madden's stress incontinence is just one among several types of urinary incontinence. The sensation of needing to urinate may be so strong that a person can't reach a bathroom in time.

For many people, medication can effectively calm an overactive bladder. But in more than half of those who try it, medication doesn't work or causes unpleasant side effects, such as dry mouth, constipation and blurred vision.

After several years of drug therapy, medication seemed to lose its effectiveness for Carol Vlack, a retired attorney who divides her time between Cleveland and Florida, where for 23 years she served as a federal public defender. She traces her problem with incontinence to the birth of her third child, John, 11 years ago when she was 45. She had two children from an earlier marriage a decade before. Today, they are 21 and 23, attending college in Sarasota, Fla.

"Having a busy, stressful job prevented me from recovering properly" after John was born, Ms. Vlack says. "He was a big baby, almost 10 pounds. That was the start of the problem."

Her days were plotted around the location of bathrooms. "I was always running for a restroom," she says. "It was embarrassing having to excuse myself 20 minutes after drinking a glass of water."

Medication kept her symptoms in check for a while, but eventually the urgency problems returned. Her doctor suggested a different drug, but the list of possible side effects made Ms. Vlack pause and seek alternatives. That's when she learned about a new device called the InterStim® neuromodulator.

The InterStim is a Food and Drug Administration–approved device to treat cases of overactive bladder that are resistant to simpler treatments. Inserted beneath the skin, the device stimulates nerves in the lower back or abdomen that control the spasms and abnormal contractions of overactive bladder.

During an hour-long procedure, electrodes are placed in contact with nerves located in front of the tailbone, as well as with the sacral nerves, which exit the spinal cord in the lower back. The pulses of low-level current are not felt by the patient.

After a two- or three-day test to make sure the device will be effective, the patient returns to the hospital to have a power pack, known as an implantable pulse generator, placed beneath the skin of the hip or lower abdomen.

"It's no bigger than a matchbook," says Ms. Vlack. "It's placed in a location where nobody is going to see unless you're wearing a bikini."

PROFESSOR MIODRAG STOJKOVIC/PHOTO RESEARCHERS, INC.

ABOVE: STEPHEN TRAVARCA; RIGHT: ALEXANDER BENZ/ZEFA/CORBIS

"This is the peak of a huge iceberg. Overactive bladder is a major quality-of-life issue. People leak into their pants and they feel like they can't leave the house. As the population ages, the problem is becoming even more common, especially among women."

— Firouz Daneshgari, M.D.

More than 25,000 people worldwide have received the device in the past decade, just a fraction of individuals with overactive bladder who could benefit from neuromodulation, says Firouz Daneshgari, M.D., Co-Director of the Center for Female Pelvic Medicine and Reconstructive Surgery at Cleveland Clinic.

"This is the peak of a huge iceberg," he says. "Overactive bladder is a major quality-of-life issue. People leak into their pants and they feel like they can't leave the house. As the population ages, the problem is becoming even more common, especially among women."

Ms. Vlack says that people need to get over the taboo of incontinence. "Most women don't want to reveal they're having this problem," she says. "It's considered an issue of aging, and it means you have some lack of control. I look at it differently; if a little technology can solve a problem, why not?"

Within four weeks of having the neuromodulator implanted in March 2007, Ms. Vlack took a 2,400-mile road trip to Sarasota. For once, there was no scramble for restrooms. She is playing tennis again, riding bikes and in-line skating with preteen John.

"Part of the reason I did this is so I can be active with him," she says. "You can't excuse yourself in the middle of a tennis game, and I don't want to tell him I can't go on a long bike ride because there are no portable potties along the way. I'm young again."

**Bruce Goldfarb** is an award-winning journalist and editor who has explored the leading edge of science and medicine for nearly 20 years. He has written for *USA Today, The Washington Post, The Baltimore Sun, American Health* and numerous other publications.

# the future of medicine

## Cleveland Clinic experts identify the top advances in medical care



The road to a medical breakthrough often starts in an unlikely place. About a century ago, one such path was forged when doctors treating cervical cancer noticed that prostitutes tended to get the disease while nuns did not. It wasn't a huge leap to suggest that sexual activity had something to do with it. By the 1970s, scientists had pinned down the agent: the common human papillomavirus (HPV), which is passed from person to person during intimate contact. Researchers began to think that if a virus causes cancer, a vaccine could stop it.

In June 2006, that vaccine got the green light from the U.S. government. Three shots of Gardasil®, a synthetic molecule that mimics the structure of HPV, prompts an immune response that protects women from HPV strains that cause more than 200,000 cervical cancer deaths worldwide every year.

Work on such cancer vaccines topped a list of 10 discoveries that experts believe will have the biggest impact on healthcare in 2007, highlighted during the Medical Innovations Summit held last fall by Cleveland Clinic. Detailed interviews were conducted with dozens of Cleveland Clinic staff members to elicit nominations for innovations produced by researchers from all over the world. A list of about 100 suggestions was pared down to 40 nominees.

A committee of physicians representing a broad range of clinical areas met to reduce the list to 22, and then a ballot was used to determine the top 10.

The results? Cancer vaccines, designer drugs and innovative depression treatments top the list. Although not exhaustive, the list offers critical insight into how new research is changing the way doctors practice the science of medicine.

### TOP 10 MEDICAL INNOVATIONS FOR 2007

1. Cancer vaccines
2. Selective receptor antagonists
3. Neurostimulation
4. Optical coherence tomography
5. Bronchial thermoplasty
6. Ranibizumab
7. Endografting
8. Targeted cancer therapies
9. Left ventricular assist devices
10. Convection-enhanced drug delivery

BY JOHN CARROLL

# TOP 10 MEDICAL INNOVATIONS FOR 2007

## 1 ON THE ROAD TO A CURE

**► CANCER VACCINES ◄** Finding a cure for cancer — the modern-day plague — is widely considered the holy grail of science. The good news is that cancer deaths in the United States have declined for the past two years, according to the American Cancer Society, thanks in large part to earlier detection, better treatment and cancer-prevention lifestyle changes, such as quitting smoking.

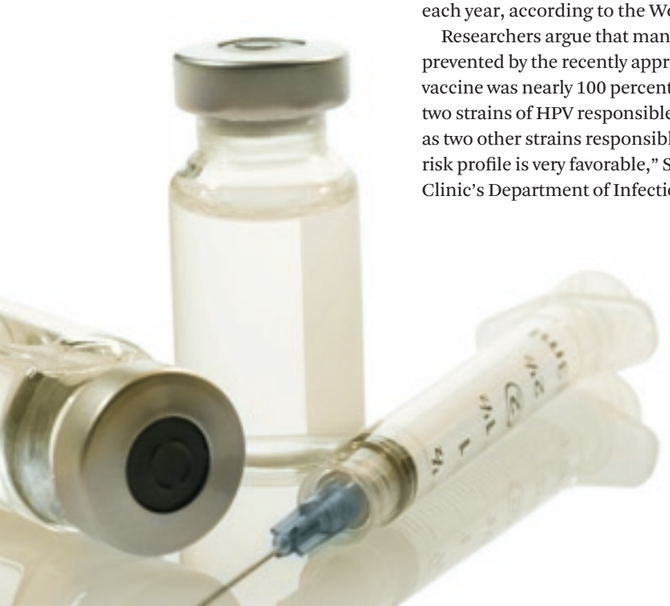
But this year alone, 1.4 million Americans will be diagnosed with some form of the disease and 560,000 will die.

The most well-publicized development in cancer vaccines is the one that protects against HPV and cervical cancer. But researchers are also working on new "therapeutic" vaccines for patients who already have cancer. These vaccines prime a patient's immune system to attack cancer cells. Prostate and pancreatic cancers are now being targeted with therapeutic vaccines in clinical trials. It's an alluring approach, but very much a work in progress: The vaccines have extended the lives of seriously ill patients by a few months but have not cured the disease or stabilized it for an extended period of time.

While that research continues, the far-reaching impact of HPV and cervical cancer remains clear. About one-quarter of American women under age 60 are infected with HPV.

Most of these infections come and go without causing any harm. But two strains of HPV are linked to cervical cancer. More than 11,000 women are diagnosed with invasive cervical cancer annually in the United States, according to the American Cancer Society, and about 3,700 American women each year will die from the disease. The problem is even greater worldwide. It's estimated that 300,000 to 500,000 new cases are identified each year; 80 percent of these are in developing countries where Pap smears are not routine. Worldwide, some 230,000 women die from cervical cancer each year, according to the World Health Organization.

Researchers argue that many future cases of cervical cancer could be prevented by the recently approved HPV vaccine. In clinical trials, the new vaccine was nearly 100 percent effective in preventing infections from the two strains of HPV responsible for 70 percent of cervical cancer cases, as well as two other strains responsible for 90 percent of genital warts. "The benefit-risk profile is very favorable," Steven Gordon, M.D., Chairman of Cleveland Clinic's Department of Infectious Disease, says of the new vaccine.



DESIGNPICS.COM/PUNCHSTOCK



SYU NAKASHIMA/GETTY IMAGES

## 2 ELIMINATING SIDE EFFECTS

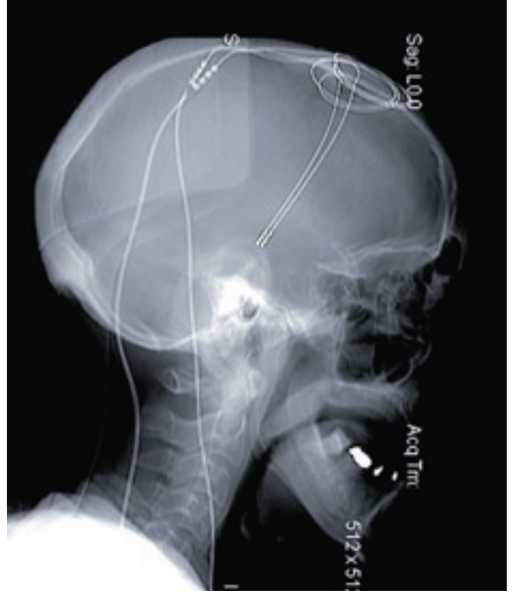
**► SELECTIVE RECEPTOR ANTAGONISTS ◄** Physicians have long struggled with prescribing medications that treat an illness but also have adverse side effects. The use of new selective receptor antagonists may provide help.

These "designer drugs" bind to receptors on the surface of cells, blocking the side effects but allowing the patient to experience the desired effect of the medication. "Receptor antagonists block side effects, opening up opportunities to go back to a proven therapy," says Marc Penn, M.D., Ph.D, Director of Cleveland Clinic's Bakken Heart-Brain Institute.

The best example is narcotics. "Obviously, narcotics block pain," Dr. Penn explains. "The problem is that they shut down the GI [gastrointestinal] tract." As a result, a patient who's just had surgery often can't eat for a long time and has to stay in the hospital for several days or weeks in a weakened condition.

"By using an opioid receptor antagonist, you can give a patient a narcotic drug and get pain relief without the unwanted GI side effect," Dr. Penn says. "You can allow patients to return to their families and to normal life much faster."

Aside from its use in narcotics, selective receptor antagonists can also aid smoking cessation efforts. Stimulating an endocannabinoid receptor heightens stress to the body, prompting patients to smoke and overeat. But selective endocannabinoid receptor antagonists can promote smoking cessation and weight loss.




3

## TREATING DEPRESSION

**▶ NEUROSTIMULATION ◀** More than 18 million Americans have major depression, and 7 million struggle with obsessive-compulsive disorder (OCD). Almost one in five is resistant to standard therapies.

Patients with severe symptoms who fail to respond to drugs, behavioral therapy or electroconvulsive therapy may benefit from an investigative device that Cleveland Clinic psychiatry and neurosurgery researchers have been studying for the past five years.

Neurostimulation uses a pacemaker-like device to deliver electrical signals through electrodes implanted into areas of the brain that regulate mood and anxiety. Using sophisticated imaging techniques and computerized surgical navigation, surgeons can pinpoint to the millimeter the correct position in the brain for implanting the brain pacemaker electrode.

"The benefits are progressive, long-lasting and sustained over time," says Ali Rezai, M.D., Jane and Lee Seidman Chair in Functional Neurosurgery and Director of Cleveland Clinic's Center for Neurological Restoration, who is collaborating with colleagues at Cleveland Clinic and Brown University on this medical advance. "The results are very promising. Two-thirds of these disabled and suffering patients have met the responder criteria for this study. Patients have benefited by improvements in mood, apathy, anxiety, energy level, interpersonal interactions and quality-of-life measures."

For now, the procedure is reserved for patients who fail to respond to standard treatments. If clinical trials continue to show positive results, brain pacemakers — which are currently used for patients with Parkinson's disease — also could become an option for patients with severe depression and OCD.

4

## VISUALIZING THE EYE

**▶ OPTICAL COHERENCE TOMOGRAPHY ◀** One of the big challenges for ophthalmologists is visualizing the fine detail of structures within the eye. Now, an imaging technique known as optical coherence tomography (OCT) is bringing everything in a patient's eye, all the way down to the cellular level, into clear focus.

OCT divides a light into two beams — a reference beam and a sample beam — to capture a cross-section view of the eye, with precision a thousand times greater than older methods.

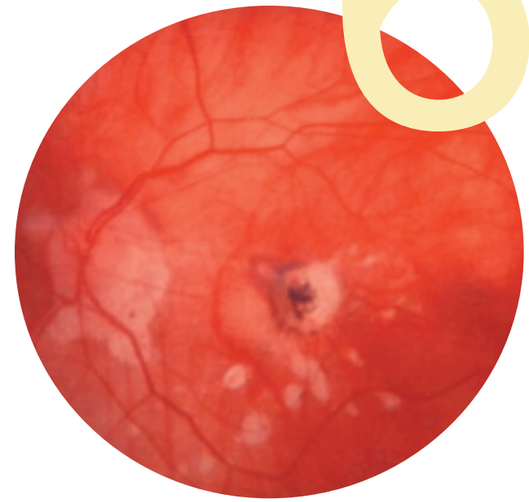
"Until now in ophthalmology, we've been able to measure to a millimeter or a tenth of a millimeter," explains Andrew Schachat, M.D., Director of Clinical Research at Cleveland Clinic's Cole Eye Institute. "Now, with this OCT device, we can measure to microns [one-millionth of a meter]. We can actually image individual cells on the retina."

The noninvasive technology can be used to better diagnose eye diseases such as diabetic retinopathy, assess a patient's response to therapy and measure various aspects of the eye with extraordinary resolution.

"We can measure the thickness of the cornea for determining how to proceed with refractive surgery, and measure to microns how large a lens implant should be," says Dr. Schachat.

LIVING ART ENTERPRISES/PHOTO RESEARCHERS, INC.

6



## SLOWING VISION LOSS

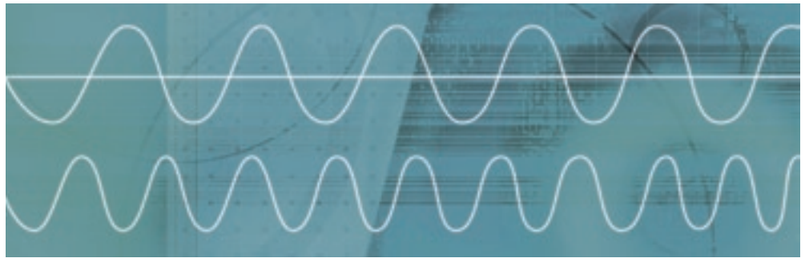
**▶ RANIBIZUMAB ◀** Age-related macular degeneration (AMD) is the leading cause of blindness in people over age 50. This loss of light-sensing cells in the center of the retina often isn't diagnosed until after the patient has lost a significant amount of vision. What's worse, currently used therapies are far from perfect. Laser therapy, for instance, can eliminate leaky blood vessels that harm retinal cells, but this helps only a small minority of patients.

A new generation of monoclonal antibody drugs offers hope to patients with the wet form of age-related macular degeneration. Last summer, the Food and Drug Administration approved ranibizumab (Lucentis®), a monoclonal antibody that binds to vascular endothelial growth factor (VEGF), a molecule that stimulates the growth of these leaky vessels. Once bound up, VEGF can't trigger new blood vessel growth.

Data from a Phase III clinical study showed that when ranibizumab was injected directly into the eye in small quantities every four weeks, vision loss slowed in 96 percent of patients. Forty percent showed significant clinical improvements in vision.

Ranibizumab has "really revolutionized treatment options," says Andrew Schachat, M.D., of Cleveland Clinic's Cole Eye Institute. "For the first time, there's vision improvement in a reasonable number of patients."

5



## ASTHMA RELIEF

**▶ BRONCHIAL THERMOPLASTY ◀** For doctors such as Thomas Gildea, M.D., a pulmonologist at Cleveland Clinic, bronchial thermoplasty represents a major advance in the treatment of Americans who suffer from asthma.

"This is the first procedure that reduces the primary source of bronchial spasm," Dr. Gildea says. That source is the smooth muscle that lines the airway. Thermoplasty is a way of safely thinning it.

The technique works like this: A flexible tube is inserted into the patient's airway, and a catheter is threaded through the tube to deliver tiny blasts of radio energy to smooth muscles that line the airway. The radio energy thins smooth muscle, causing only minimal, transient injury to the tissue. In clinical trials, the method has reduced this muscle layer by 50 percent.

Once airway muscle is thinned, it isn't as sensitive and is less likely to spasm. The procedure is quick — it takes less than 30 minutes — and can be done on an outpatient basis with only a light anesthesia.

A clinical trial of the technology is under way involving several hundred patients in some 30 sites. Dr. Gildea is optimistic that bronchial thermoplasty will help transform the treatment of asthma, which affects approximately 20 million Americans, according to the American Lung Association.

PHANIE/PHOTO RESEARCHERS, INC.

## 7 MINIMALLY INVASIVE TREATMENT

**▶ ENDOGRAFTING ◀** An aneurysm is an abnormal bulge or enlargement of the artery. An aneurysm affecting the aorta — the body's main artery — is particularly serious because if it ruptures, it is usually fatal. About 5 percent to 7 percent of Americans over age 60 will develop an aortic aneurysm, and rupture is the No. 13 cause of death in older Americans.

The traditional treatment of an aortic aneurysm involves surgery to replace the affected blood vessel with synthetic material. This surgery carries the risk of such complications as bleeding, lung or heart failure, and paralysis. Endovascular grafts, which have been commercially available since 1999, offer a minimally invasive alternative but have been limited to patients with aneurysms in a particular part of the aorta.

A new technique, called endografting, is also minimally invasive but uses endovascular grafts that allow treatment in hard-to-reach areas. The result is a relining of the aorta with side "arms" that reach the aortic branches to the intestines, kidneys or brain. The arms, made of wire-mesh endovascular stents and polyester fabric, prevent pressure that could rupture the aneurysm.

Endografting may be done under local, regional or general anesthesia, even when the aneurysms are close to the heart.

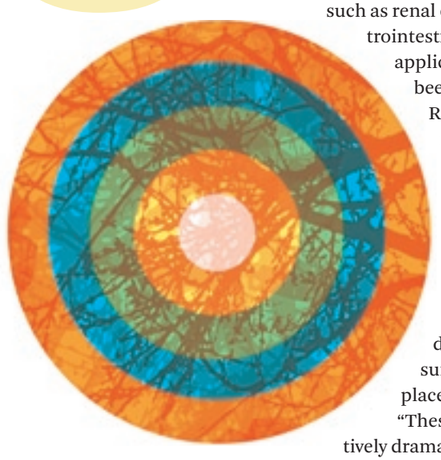
"That we would be able to do such complex procedures with a minimally invasive approach, even with the patient awake, once seemed beyond the realm of possibility," says Cleveland Clinic vascular surgeon Roy Greenberg, M.D. "It's changing the way people think."

Commercial devices are already available in Europe and Australia; clinical trials are under way in the United States.

## 8 CUTTING A TUMOR'S LIFELINE

**▶ TARGETED CANCER THERAPIES ◀** A number of cancers produce vascular endothelial growth factor (VEGF) to spur the growth of new blood vessels. But the recently approved drug sunitinib (Sutent®) and other tyrosine kinase inhibitors (TKIs) are targeted cancer therapies that block VEGF receptors in blood vessels. They essentially starve tumors of blood and tissue.

TKIs have proved to be valuable therapies for rare and lethal cancers such as renal cell carcinoma and gastrointestinal stromal tumors. "Its application in kidney cancer has been reasonably dramatic," says Robert Dreicer, M.D., Chairman of Cleveland Clinic's Department of Solid Tumor Oncology. Data on clinical trial volunteers who stay alive without their disease worsening are encouraging.



In one recent clinical trial, patients taking a TKI drug had progression-free survival rates twice that of the placebo group.

"These agents demonstrated relatively dramatic changes in the natural history of the disease," says Dr. Dreicer. "What we are about to see is an explosion and a change in how we approach the management of many epithelial cancers."

## 9 HELP FOR YOUR HEART

**▶ LEFT VENTRICULAR ASSIST DEVICES ◀** Thousands of Americans develop heart failure every year. This occurs when the damaged heart, specifically the left ventricle, is unable to supply all the blood needed by the body. For many patients, heart transplantation is the only solution, but 10 percent to 15 percent of patients awaiting heart transplantation die before receiving a new heart.

Increasing numbers of patients with severe heart failure are benefiting from left ventricular assist devices (LVADs) — mechanical pumps that help the heart circulate blood throughout the body. First-generation LVADs were large and unreliable. Newer devices are much smaller and more reliable and remain capable of pumping the same volume of blood as the larger devices.

Results with the new devices have been promising. Like a bridge, the LVAD supports patients until a heart becomes available for transplantation. The devices have fewer moving parts and are designed to last 10 to 12 years. Recent trials of these smaller pumps have shown fewer complications, especially infections, compared with older versions, says Nicholas Smedira, M.D., Surgical Director for Cleveland Clinic's Kaufman Center for Heart Failure.

GLENN PIERCE

## 10 BRAIN-TUMOR BREAKTHROUGH

**▶ CONVECTION-ENHANCED DRUG DELIVERY ◀** The goal for any doctor treating a brain tumor is to remove all of the tumor while sparing as much precious healthy brain tissue as possible. Doctors and patients have had to rely on surgery and radiation therapy to accomplish this because chemotherapy, a mainstay of cancer treatment in other parts of the body, has been thwarted by the blood-brain barrier. This usually helpful barrier is a mechanism that keeps many drugs trapped inside small blood vessels and prevents them from reaching tumor targets in the brain.

A technique called convection-enhanced delivery (CED) may take therapies into new territory by overcoming the blood-brain barrier. CED is the continuous injection of fluid containing a therapeutic agent into the brain under positive pressure. A special catheter delivers chemotherapy directly to the site of the tumor.

Another major advantage of CED is its ability to reach cancerous cells that have invaded beyond the tumor, possibly stopping the spread of disease. The technology allows the blood-brain barrier to work for the patient by keeping chemotherapy inside the brain. After years of testing, neurosurgeons believe that the first CED-delivered drug may be approved in the United States in the near future. The initial research on malignant brain tumors is being followed up with programs testing drug delivery for epilepsy, enzyme replacement therapy, stroke, movement disorders and spinal cord injury.

"We're going to be seeing a lot more of this technology in the near future," says Michael Vogelbaum, M.D., Ph.D., Associate Director of the Brain Tumor and Neuro-Oncology Center at Cleveland Clinic, who directed a symposium on CED this spring in Cleveland.

GLENN PIERCE

**John Carroll** is a veteran healthcare and biotechnology writer. He is Senior Contributing Editor for the journal *Biotechnology Healthcare* and Editor of *FierceBiotech* and *FierceBioResearcher* e-mail newsletters.

For an up-close look at innovation in action, go to **clevelandclinic.org/ccm**.

TODAY'S **INNOVATIONS** → TOMORROW'S **HEALTHCARE**

CAMPAIGN FOR CLEVELAND CLINIC

The Sydell and Arnold Miller Family Pavilion will open in 2008 as the new home of Cleveland Clinic's Heart and Vascular Institute.

YU KWAN LEE

# CAMPAIGN SUPPORTERS SET A RECORD WITH $45 MILLION IN THE FIRST QUARTER

On May 8, 2006, Cleveland Clinic announced a campaign to raise $1.25 billion by 2010. It was an ambitious goal, even for an institution dedicated to setting the bar high. With supporters rising to the challenge, 2007 saw Cleveland Clinic record its best-ever first quarter of fundraising with $45 million.

"We are pleased that so many of our friends have stepped forward to ensure the future of Cleveland Clinic care," says Delos M. Cosgrove, M.D., Cleveland Clinic President and CEO. "They are providing the leadership and support that will allow us to take medicine to the next level."

Supporters of *Today's Innovations, Tomorrow's Healthcare: Campaign for Cleveland Clinic* have contributed more than $875 million toward the campaign's goal. Across Cleveland Clinic, patients and visitors can witness this immense generosity in action.

On the main campus, the Sydell and Arnold Miller Family Pavilion is rapidly taking shape as the future home of Cleveland Clinic's world-renowned Heart and Vascular Institute. Giving is enhancing the education and fellowship program, as well as state-of-the-art equipment, at the Spine and Neuromuscular Center at Cleveland Clinic in Florida. At Cleveland Clinic Children's Hospital, a gift has led to the creation of a Leadership Chair for Excellence in Pediatric Care, Research and Education.

Philanthropists are supporting the advancement and enrichment of care at every turn. They are a key part of the future of healthcare, and their continued dedication is helping Cleveland Clinic as it sets the pace of innovation.

For more information on **Today's Innovations, Tomorrow's Healthcare: Campaign for Cleveland Clinic** or to make a donation, visit **clevelandclinic.org/giving**. Send e-mail to campaign@ccf.org or call 216.444.1245.





# LARGEST FLORIDA GIFTS MADE IN LOVING TRIBUTE

## John and Margaret Krupa's support reaches more than $16 million

Margaret Krupa

ALEX GORT

Margaret Krupa was waiting tables as a teenager in Charleston, W.Va., when she met her late husband, John. Their chance meeting led to a close-knit marriage that lasted half a century.

"I served him breakfast and that was it. I ended up cooking his meals for the next 50 years," she says with a laugh.

Together, they advanced Safety Sign Company, a manufacturer of signs, tags and labels in Strongsville, Ohio. They worked together, often for long hours each day, for 49 years. Long before the Occupational Safety and Health Administration formalized regulations, the Krupas' signage protected people from machine and road hazards.

The Krupas' concern for the welfare of others extended to charitable giving. Mrs. Krupa says philanthropy, like their professional life, became a passion for her and her husband. She says they would sit in the kitchen together after a long day, and he would talk about the wider significance of charitable giving. She recalls her husband's excitement about helping others through the John and Margaret Krupa Charitable Foundation.

> "John had a vision that was large and loving, and he really wanted all the work we did to matter, to help people who may not be able to help themselves." — Margaret Krupa, speaking of her late husband

After celebrating their 49th wedding anniversary, Mr. Krupa passed away in March 2002.

Mrs. Krupa smiles as she remembers her husband, who drew great pleasure from seeing resources put to good use. In his memory, Mrs. Krupa recently gave more than $6 million to Cleveland Clinic in Florida through their foundation. With this gift, the Krupas' giving totals more than $16 million — the largest philanthropic commitment in the history of Cleveland Clinic in Florida.

"John had a vision that was large and loving, and he really wanted all the work we did to matter, to help people who may not be able to help themselves," Mrs. Krupa says.

This is not the first time she has honored her husband. In 2001, she gave $8 million as a loving tribute to Mr. Krupa. It established an endowed chair in Geriatric Medicine held by Jerry O. Ciocon, M.D., and funded medical education fellowships and research to find effective treatments for geriatric problems, such as Alzheimer's disease. This commitment also enabled the completion of Cleveland Clinic in Florida's Spine and Neuromuscular Center, known as The Margaret and John Krupa Neurological, Skeletal and Spine Pavilion.

Mr. Krupa, who had endured a stroke and whose mother had Parkinson's disease, understood what it meant to live with these conditions.

"I wanted to give a gift that would mean something to John. I believe in helping older people, who I think sometimes feel forgotten. John and I always thought they should have the opportunity to receive the best care, stay independent and maintain their dignity," Mrs. Krupa says.

In November 2000, the Krupas together gave $2 million to establish the first endowed chair in Neurology at Cleveland Clinic in Florida through the Krupa Charitable Foundation. Virgilio D. Salanga, M.D., M.S., former Chairman of Neurology, continues to serve as the first chair holder. With this gift, the Krupas supported clinical care of patients, research and teaching of residents and fellows.

It is Mrs. Krupa's fondest wish that her husband be remembered. She hopes that people might see his name on the sign for the pavilion and say a prayer for him.

# ZAPIS GIFT HONORS WIFE AND MOTHER

## A $1.5 million contribution endows a breast cancer research chair

Xen and Lula Zapis made emigrants from their native land of Greece feel like family on their arrival to Cleveland.

"I always feel for people who come from Greece and can't find their way around. I would tell them, 'If you need to go to the doctor and you can't get there, I'll take you,'" says Mrs. Zapis.

Over the years, she arranged appointments and personally escorted many people to Cleveland Clinic. Her offer to help was made in an unconventional way: She broadcast it on the radio.

For 30 years, she and her husband ran a half-hour nightly radio program for people of Greek descent. Mr. Zapis started the program in 1949, offering discussions of immigration and other real-life problems. He often was hailed as "the unofficial Greek ambassador."

Mrs. Zapis shared this role, assisting relatives who traveled from Greece to receive treatment at Cleveland Clinic for serious health conditions.

"I met many doctors, the best you can find. As I learned more and talked to more people at Cleveland Clinic, my desire to contribute to its future and success grew," she says.

Then, in 1993, Mrs. Zapis was diagnosed with breast cancer and found herself at Cleveland Clinic for treatment. Her cancer went into remission.

"I think of all the women who had to go through what I went through with breast cancer. I want them to find comfort and treatment," Mrs. Zapis says. "I told my family, 'We should do something to help.'"

So, Mr. Zapis and his children made a surprise gift in honor of Mrs. Zapis, which established the Lula Zapis Endowed Chair in Breast Cancer Research. The $1.5 million chair supports the research of chair holders G. Thomas Budd, M.D., and Joseph Crowe Jr., M.D.

As part of the Molecular and Genetic Markers in Breast Cancer Research Program, their research focuses on personalizing breast cancer care through a better understanding of genetics.

Dr. Budd explains, "There are two 38-year-old women with the same kind of cancer. They get the same treatment, but one survives and one dies. We want to find out why."

Mrs. Zapis could not be happier about her family's gift. "Supporting breast cancer research is important, not so much for me, as I am in remission. But I have daughters, and there are other people's daughters, other women. I wanted to do something for them."

The Zapis family has a tradition of giving to Cleveland Clinic. Besides other offerings, they made a gift to the Greece Educational Program, making Cleveland Clinic medical expertise available to the people of Greece. The Zapis' philanthropy also extends into the local community as the Zapis Charitable Foundation supports Christian, educational and healthcare organizations in northeast Ohio.

Mrs. Zapis credits her family for inspiring her passionate philanthropy. During the Greek Civil War in the 1940s, she witnessed her grandmother's generosity.

"Every evening before dinner, my grandmother would have something tucked under her apron and she would say, 'I'll be back.' She never told us, but we knew she shared food with our neighbors. She knew who needed help. To me, there is nothing as important as philanthropy."

"I met many doctors, the best you can find. As I learned more and talked to more people at Cleveland Clinic, my desire to contribute to its future and success grew." — Lula Zapis

Xen and Lula Zapis

PENNY TAYLOR

# PHILANTHROPISTS BOLSTER CARDIAC CARE RESEARCH

## Kenny Gee and Paula Shaw, Ph.D., establish $1 million research chair to help solve heart's mysteries

When Kenny Gee learned that he had developed a descending aortic aneurysm, or bulging in the body's largest artery, he and his wife, Paula Shaw, Ph.D., acted quickly. This serious condition put Mr. Gee at risk for a ruptured aorta. To find the best place for treatment, the couple consulted with health professionals in Washington, D.C., where they reside, and did extensive research.

"I was concerned about taking too much time searching, but everything we heard and read led us straight to Cleveland," says Mr. Gee, a retired business executive.

They traveled to Cleveland for Mr. Gee's procedure last winter. Now, they say they will never forget their initial meeting with Bruce W. Lytle, M.D., Chairman of Cleveland Clinic's Department of Thoracic and Cardiovascular Surgery.

"Dr. Lytle had such an easygoing manner. He spent 45 minutes with us, explaining," Dr. Shaw recalls, adding that he was down-to-earth and approachable, allaying much of their anxiety.

After Dr. Lytle performed the surgery, Mr. Gee spent seven days in recovery. Having spent 35 years implementing management strategies at Xerox Corp., Mr. Gee deliberately noted the details of how his healthcare was managed.

"Believe me, I had time to notice," he says with a laugh. "They did things right and did them right every time; that's quality and excellence. I saw it in the details of my care. Everything was managed to perfection."

As thanks, the couple is supporting cardiac care at Cleveland Clinic. Their $1 million contribution has established The Kenneth Gee and Paula Shaw, Ph.D., Term Chair in Heart Research. Their gift, made in honor of Dr. Lytle, will assist the investigative pursuits of Cleveland Clinic cardiovascular surgeon Eugene Blackstone, M.D., the first physician to hold the chair.

"We had so much gratitude for Dr. Lytle. And we wanted to do something to help other heart patients," Dr. Shaw says, adding that she and her husband were glad to make this gesture in their lifetimes rather than through their will.

Dr. Blackstone and his colleagues perform research using the Cardiovascular Information Registry, which contains data concerning nearly 200,000 Cleveland Clinic patients.

Dr. Blackstone says, "We not only treat those who come through our doors, but with this kind of support, we can help patients all over the world. We can study which heart treatments work best and publish our findings for other doctors. Working at the busiest cardiovascular center in the country, we see a large number of patients with complex problems, can study their outcomes of surgery and investigate how they should best be treated."

Mr. Gee and Dr. Shaw, a clinical psychologist, call themselves "self-made people." Dr. Shaw, who serves at the helm of Altos Federal Group, a medical staffing company, describes her upbringing.

"We had modest roots. My dad was a steelworker and my mom worked for the government. We think it's important to be humble in life and help others. The mind-set we have is that you need to do things beyond yourself," she says.

Paula Shaw, Ph.D., and Kenny Gee

"We had so much gratitude for Dr. Lytle. And we wanted to do something to help other heart patients." — Paula Shaw, Ph.D.

TOM MERCE

# SUPPORTERS HOPE TO CONQUER CANCER AND HELP HEART PATIENTS

## Al and Norma Geller contribute $1 million to support research

Al Geller asked his wife, Norma, to name her birthday wish. She did not ask for flowers or jewelry, but to attend a cancer researcher's lecture. An ovarian cancer survivor, Mrs. Geller has a passion for fighting disease — an enthusiasm her husband shares. Every birthday is a celebration of this personal cause.

Mrs. Geller could not anticipate the impact of her routine doctor's visit 16 years ago when her Cleveland-area physician asked if she would participate in a research project involving a blood test. Believing in sharing what you can with others, she agreed. The test, which she would not have received otherwise, led to an ovarian cancer diagnosis followed by successful treatment. When her physician left the area, she transferred to Jerome Belinson, M.D., Obstetrics and Gynecology, Cleveland Clinic, for ongoing care.

"Although he didn't operate on me, Dr. Belinson is keeping me healthy. I'm very grateful for the care I received," Mrs. Geller says.

Mr. Geller also has turned to Cleveland Clinic for help. After Mr. Geller felt a burning in his chest while playing tennis, A. Michael Lincoff, M.D., a Cleveland Clinic cardiologist, found several blockages in his heart.

Because Mr. Geller had never had a heart attack and was otherwise in exceptional physical health, his medical team suggested a technically difficult type of quadruple bypass surgery, allowing for the use of his own arteries. Arteries are sturdier and wider than veins and less apt to form new blockages.

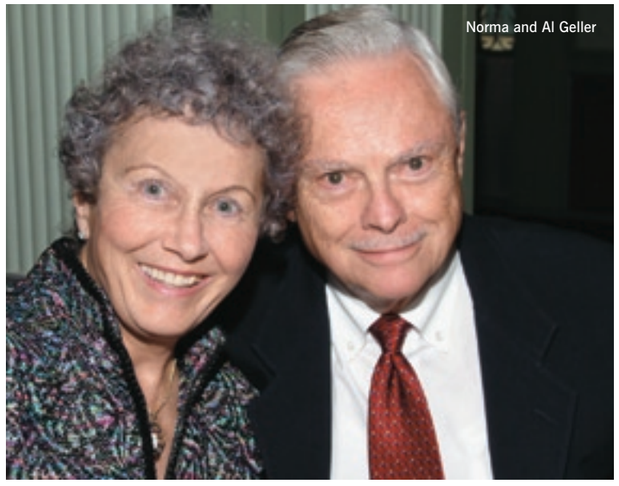
"We would never have known about this procedure if it was not suggested to us. I greatly appreciate the expertise of Cleveland Clinic," Mr. Geller says.

The Gellers hope to help other patients. They recently made a $1 million commitment to support cancer and cardiovascular research in three key areas at Cleveland Clinic.

They are helping sustain the work of Ram Ganapathi, Ph.D., in ovarian cancer research advances through the Focused Innovative Strategies and Hypothesis (FISH) Ovarian Cancer Research Fund, which they established with another gift in 2004. Their recent gift also supports the research of Michael Vogelbaum, M.D., Ph.D., who is seeking new therapies for malignant brain tumors, and it fuels the cardiac research of Dr. Lincoff.

"This is the Geller philosophy: We act when we see a need. We hope to make a difference in people's lives," Mrs. Geller says.

The Gellers, owners of Cleveland-based Fish Furniture, support cancer care in many ways, including contributing their time and experience to the Taussig Cancer Leadership Board. And, after volunteering for 20 years in hospital settings, Mrs. Geller, mother of four, went to college at age 45 to become an oncology social worker. The Gellers also helped found a branch of the Wellness Community, offering support for cancer patients and their families in Boca Raton, Fla., near the Gellers' winter home.


Norma and Al Geller

DON GERDA

"This is the Geller philosophy: We act when we see a need. We hope to make a difference in people's lives."

— Norma Geller

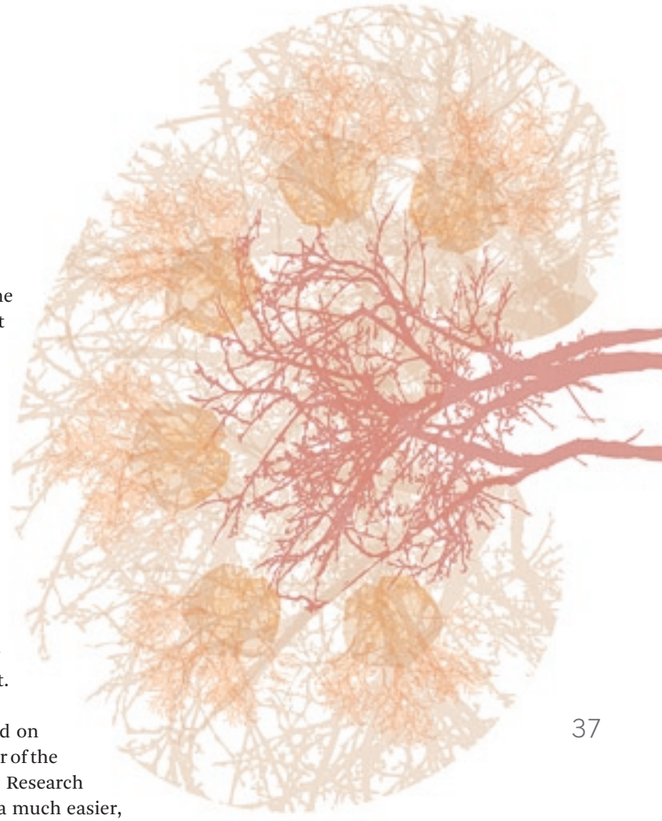
— PHILANTHROPIA PROFILES BY MICHELLE TACKLA







# Beyond Dialysis



Today's kidney dialysis machines are destined for the medical history books, like the iron lung that kept so many polio sufferers alive in the mid-1900s. Working on an ultra-small scale, researchers are developing an implantable device that will function much like a natural kidney, without requiring the patient to be hooked up to a dialysis machine for hours at a time.

For the more than 300,000 Americans with end-stage renal disease (ESRD) who depend on dialysis to cleanse their blood of waste normally eliminated by the kidneys, dialysis is an effective stopgap measure — not a long-term solution. On average, people survive on maintenance dialysis for about five years.

Kidney transplantation is a permanent fix for ESRD, but fewer than 15 percent of people on dialysis receive a kidney transplant. And demand for kidneys is increasing.

"There's an unmet need among ESRD patients who depend on dialysis for their survival," says William H. Fissell, M.D., Director of the Renal Nanotechnology Laboratory at Cleveland Clinic Lerner Research Institute. Dialysis patients need better waste removal — and a much easier, less costly way to get it done.

Dialysis has an annual cost of almost $65,000 per patient, and people undergoing treatment can be prone to accelerated cardiovascular disease, as well as an infection rate 20 times that of the general population. Technology being developed by Dr. Fissell and his Cleveland Clinic collaborator, Shuvo Roy, Ph.D., one day may overcome many of the disadvantages that exist for people on dialysis today.

With nanotechnology — the science of manipulating materials on a very small scale — and microelectromechanical systems (MEMS), Drs. Fissell and Roy, Co-Director of the BioMEMS Laboratory, along with a team of specialists, are designing miniaturized membranes for an implantable device that will filter waste and impurities from blood. Their research holds the promise of a viable artificial kidney.

"These technologies allow us to engineer filtering membranes powered solely by the cardiovascular system," says Dr. Fissell. For dialysis patients, that means the days of being tethered to a large dialysis machine could come to an end.

The pores of the artificial kidney membrane are about 10 nanometers wide — 10,000 times smaller than the diameter of a human hair. As the membranes mimic the natural function of the kidney, researchers say blood could be moved through it by the body's normal blood pressure without the need for an external pump or power source.

Researchers are evaluating membranes and concept devices in the lab.

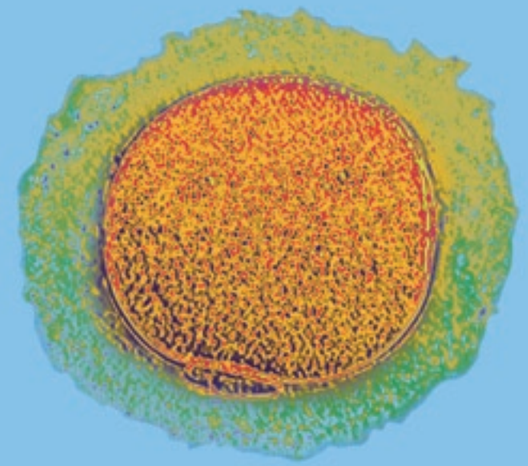
"We believe that in a 10-year time frame, and with sufficient resources, we can have something that can be implanted in patients," says Dr. Roy.

— BRUCE GOLDFARB

TOM KAZENSKE

Dialysis has an annual cost of almost $65,000 per patient, and people undergoing treatment can be prone to accelerated cardiovascular disease, as well as an infection rate 20 times that of the general population.

# A fertility treatment that could bypass the hormonal blitz



For many women struggling to conceive, in vitro fertilization (IVF) has been the answer to infertility. And successful results can make the miracle of life seem even more miraculous. But IVF is a multistep process that begins with two weeks or more of hormonal injections that can make some women very uncomfortable.

Now, hopeful parents could one day have an option that sidesteps that hormonal barrage.

The procedure, called in vitro maturation (IVM), still uses a woman's eggs, but the eggs mature in the laboratory rather than in the woman's body. The technique requires little or no hormonal stimulation, which means patients can avoid many side effects.

In IVM, several immature oocytes, or egg cells, are retrieved from a woman's ovary, then matured in the laboratory for 24 to 48 hours. The resulting embryos can be fertilized through sperm injection and then transferred to the woman's womb. They also can be frozen for use at a later date.

Cynthia Austin, M.D., a gynecologist at Cleveland Clinic's Beachwood Fertility Center, and her colleagues are among a small group of fertility specialists working to perfect IVM so that it may become a readily available option for women who face a range of fertility challenges.

"Some patients don't tolerate hormonal stimulation well, and they might benefit from IVM," Dr. Austin says.

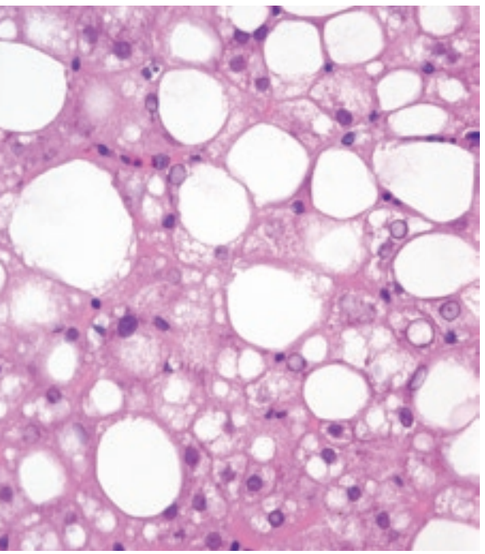
IVM was first evaluated in women with polycystic ovary syndrome, a hormonal disorder that impedes fertility; it is now being tested in a wider group. Women who have not had success with IVF, as well as patients with poor egg quality after hormone therapy, may be candidates.

Cancer patients, too, may benefit. Because certain chemotherapy drugs can destroy egg cells, cancer patients who wish to preserve their eggs or embryos before they undergo cancer treatment may be candidates for IVM. The procedure may be appropriate for egg donors as well, enabling them to donate eggs to infertile couples without going through the extensive hormone treatments.

Progress toward IVM as a routine clinical technique has moved rapidly in recent years, after decades of research. Laboratory maturation was shown to work in human cells in 1965, but the first human birth from in vitro–matured oocytes did not occur until 1991. Today, some 500 children worldwide have been born using the technique.

— LOLA BUTCHER

# Gentler liver tests for kids



AJPHOTO/PHOTO RESEARCHERS, INC.

Twenty years ago, liver disease was virtually unheard of in children. But today, physicians routinely see what was once unthinkable: Overweight young people with cirrhosis of the liver, the irreversible damage most often associated with long-term alcohol abuse.

Nonalcoholic fatty liver disease (NAFLD), the accumulation of fat in the liver, has become the most common chronic liver disease in both children and adults, affecting an estimated 15 percent to 20 percent of young people ages 12 to 18 and 30 percent of adults. NAFLD alone is not considered dangerous, but in some people, it can progress to a serious condition called nonalcoholic steatohepatitis (NASH), an inflammation of the liver that destroys the organ's cells. The condition resembles alcoholic liver disease but occurs in patients who drink little or no alcohol. As many as 25 percent of patients with NASH progress to cirrhosis and can have complications such as liver failure and liver cancer.

Until recently, only a liver biopsy could distinguish between harmless NAFLD and nonalcoholic steatohepatitis. But many children and young adults at risk for NASH simply reject undergoing a liver biopsy, which requires a six-inch needle inserted through the abdomen to obtain a sample of liver tissue. Possible complications from the procedure include bleeding and adverse reactions to anesthesia. And in children, a liver biopsy typically involves an overnight hospital stay.

A group of physicians at Cleveland Clinic, led by Ariel E. Feldstein, M.D., in the Department of Pediatric Gastroenterology and Cell Biology, recently developed a simple blood test that can accurately identify NASH in both children and adults without a costly, uncomfortable biopsy.

"A biopsy is a serious and scary thing, and as a result, there is widespread unwillingness to undergo it," says Dr. Feldstein. "But the new test is so simple it means primary care physicians across the country will be able to use it to quickly and easily distinguish between NAFLD, the benign fatty liver condition, and NASH."

Earlier detection, in turn, should mean more effective intervention and improved outcomes for NASH patients. Treatment for NASH includes counseling to reduce weight, eating a balanced diet, engaging in physical activity and avoiding alcohol and unnecessary medications.

Dr. Feldstein's team developed the blood test after finding that a specific fragment of a protein called cytokeratin-18 was present in the blood of only patients with NASH.

A study of the test in nearly 400 patients at eight U.S. medical centers is under way, Dr. Feldstein says.

Providing the results are promising, he hopes to see the test approved for widespread use within the next one to two years.

— BONAR MENNINGER

# HOPE FOR EPILEPSY PATIENTS

When medication fails and seizures are uncontrollable, children with epilepsy have few options. Sometimes brain surgery can help, but doctors move cautiously before going ahead with such serious treatment.

"We want to make sure we do no harm," says Elaine Wyllie, M.D., a pediatric epilepsy specialist at Cleveland Clinic Children's Hospital. "But some people suffer for a long time before getting surgery."

New research by Dr. Wyllie and her colleagues at Children's Hospital may help physicians more quickly and effectively identify those patients who will benefit from surgery.

Traditionally, two tests taken together are especially important to doctors as they decide which patients are eligible.

The first is an electroencephalograph (EEG), or brain-wave reading. A normal EEG looks like a continuous, wavy line. For some patients, the wavy line will spike in certain places, indicating the seizures come from a focal "trigger zone" in the brain.

The second test, magnetic resonance imaging (MRI), produces detailed pictures of the brain and can reveal a lesion related to the seizures.

When the MRI shows a lesion *and* the EEG indicates a trigger zone, doctors usually feel they have enough information to commit to surgery. Typically, only some infants are considered eligible for surgery without strong evidence on the EEG of a trigger zone.

Dr. Wyllie's research has shown that, even with no obvious trigger zone on EEG, surgery may be a viable option for some children. A certain type of focal lesion seen on MRI — one that doctors recognize as having occurred or formed in early brain development — may be the key to successful surgery.

> "There's a certain population of children we thought was ineligible for surgery. …We may have a solution for them."
> — Elaine Wyllie, M.D.

Dr. Wyllie and her colleagues studied 50 children and adolescents with profound epilepsy who did not appear to be favorable candidates for surgery because their EEGs did not pinpoint a clear trigger zone. However, their MRIs showed a focal lesion acquired in early brain development.

The surgeries, which were performed as a last resort, resulted in no mortalities, and 72 percent of the patients became seizure-free.

"What this shows," Dr. Wyllie says, "is that the key is not the patients' age when they're evaluated for surgery but whether the lesion found on MRI occurred in infancy or before."

Dr. Wyllie, who presented her findings May 1 at the annual meeting of the American Academy of Neurology, is excited about what this may mean for children and teens with uncontrolled seizures. But she stresses more research is needed to establish a firm connection between the type of lesion and whether epilepsy surgery will be successful.

"There's a certain population of children we thought was ineligible for surgery," she says. "It turns out that we may have a solution for them."

— TRICIA SCHELLENBACH

# Treating ED

Drogo Montague, M.D., answers questions about erectile dysfunction

**It used to be something no one talked about.** Today, the topic of erectile dysfunction is no longer taboo. The repeated inability to get or keep an erection for sexual intercourse affects about one in five American men. In recent years, the release of well-publicized medications to treat this condition has led to an increase in the number of physician office visits related to ED.

### In terms of sexual performance, what is normal?

**A** ▶ Although men can remain sexually active throughout their lives, their sex life probably won't be the same at age 70 as it was at 20. As men age, getting an erection takes longer, and the erection may not be as firm as it used to be. But if they're healthy, it will be firm enough for intercourse.

When a man has an orgasm, his erection goes down more quickly when he's older, and the refractory period — the time until he can get an erection again — gets longer with age. The volume and force of ejaculate decrease as well.

### How would you describe your typical patient?

**A** ▶ The majority of men we see were sexually active for most of their lives, then slowly developed trouble with erections as they aged. In these circumstances, erectile dysfunction is almost always due to an underlying problem — often vascular disease. Or men can develop ED after prostate or rectal surgery.

We also do see some young men who have ED with no apparent disease. Under those circumstances, it's usually psychogenic — mental or emotional. Not many young men have this problem.

### How has the treatment of erectile dysfunction evolved?

**A** ▶ Since 1973, penile implants have been available for men with diabetes and cardiovascular disease, as well as those who develop ED after surgery. Penile implant surgery is most of what I do here. Although implants are the oldest of the treatments, new antibiotic coatings and design changes have made the devices last longer. But the principle is the same.

In 1983, penile injections of prostaglandin — a vasodilator — came on the horizon. Vasodilators are medicines that act on muscles in blood vessel walls to make the vessels widen. Men had to learn how to give themselves a shot in the penis with a tiny needle directly into the erection chambers. That gave men an option. They avoid surgery by learning to inject themselves every time they have intercourse.

The third sentinel event was the introduction of PD-5 inhibitors, such as Viagra®, in 1998. Viagra works by increasing the flow of blood to the penis so that when a man is sexually stimulated he can get an erection.

### The introduction of Viagra seems to have made it easier for men to talk about erectile dysfunction.

**A** ▶ We are seeing a lot of men come forward to talk about ED because of the pills. They're typically in their 40s or 50s, they're hypertensive and they have high cholesterol levels and a lot of risk factors. These men usually aren't seeing a doctor and they have ED because they have undiagnosed cardiovascular disease. ED is being used as a marker for cardiovascular disease.

**Drogo Montague, M.D.,** Section Head of Prosthetic Surgery and Genitourethral Reconstruction at Cleveland Clinic Glickman Urological and Kidney Institute.

We are seeing a lot of men come forward to talk about ED... . They're typically in their 40s or 50s, they're hypertensive and they have high cholesterol levels and a lot of risk factors.

### Talk more about penile implants. Is the surgery under general or spinal anesthesia?

**A** ▶ About 20,000 penile implant procedures are done in the United States annually, and that has remained fairly constant. We do about 70 penile implants a year at Cleveland Clinic.

There have been a lot of advances in implant surgery over the years. The best devices now expand not only the diameter but the length as well, producing an erection closer to a natural erection. The infection rate is below 1 percent with antibiotic coatings.

Penile implant surgery is an outpatient procedure under general or spinal anesthesia. Men stay overnight in the outpatient surgical facility. There's one incision, no tissue is removed and blood loss is minimal.

STEPHEN TRAVARCA

### How does the penile implant work?

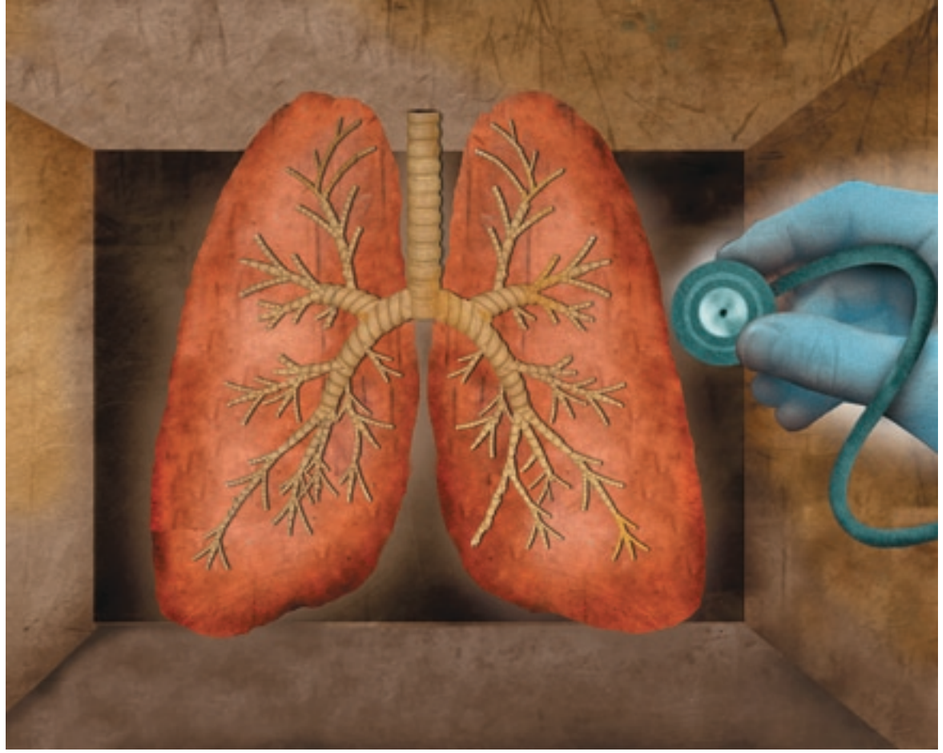
**A** ▶ The inflatable penile prosthesis consists of two cylinders — a reservoir and a pump — that are placed surgically in the body. The two cylinders are inserted in the penis and connected by tubing to a separate reservoir of fluid. The reservoir is implanted under the groin muscles. A pump is also connected to the system and sits under the loose skin of the scrotal sac, between the testicles.

To inflate the prosthesis, the man presses on the pump. This does not involve putting pressure on the testicles. The pump transfers fluid from the reservoir to the cylinders in the penis, inflating them. Pressing on a deflation valve at the top of the pump returns the fluid to the reservoir, deflating the penis.

### Are patients reluctant to consider penile implant surgery?

**A** ▶ If you look at patient preference, and you ask patients whether they'd prefer shots, pills or implants, most would say they prefer a pill. But not every treatment is effective for everybody. Penile implants work for a higher percentage of men than any other kind of treatment. And for some men, it's the only thing that's going to work. — BRUCE GOLDFARB

Get the vital stats on ED at **clevelandclinic.org/ccm**.



MICHAEL MORGENSTERN/THEISPOT.COM



# Ultrasound Gives Doctors a New Tool in the Hunt for Tumors

It was around Thanksgiving when Guerry Stribling learned that he had cancer of the pyriform sinus, an area behind the base of his tongue. The disease was advanced — stage four. "They had to nearly kill me with the radiation and the chemotherapy to get rid of it," says Mr. Stribling, 73, of Wellington, Fla.

About six months after Mr. Stribling finished a combined course of 35 radiation and chemotherapy treatments in the fall of 2006, a scan revealed the good news that his original tumor was gone. It also picked up a suspicious spot on a lymph node outside his bronchial tube. The oncologist needed a biopsy to know if it was malignant, but getting the tissue sample wasn't going to be easy.

The bronchial tubes sit behind the sternum and ribs, where the heart and vital blood vessels nestle near the airway, lungs and lymph nodes. It can be a difficult place to maneuver. A conventional bronchoscope — a long, thin, lighted tube inserted through the throat with a needle to remove a small sample of tissue — forces doctors to work "blindly." In Mr. Stribling's case, it could not pinpoint the spot well enough to get the sample. And open surgery was not the best option for someone still recovering from rigorous cancer therapy. Mr. Stribling's doctor recommended instead that he try a new diagnostic procedure.

Eduardo C. Oliveira, M.D., a pulmonology and lung cancer specialist at Cleveland Clinic in Florida, used ultrasound to guide him to the right spot. With this outpatient procedure, called endobronchial ultrasonography (EBUS), doctors can precisely guide the needle to collect those hard-to-reach samples of tissue in a patient's chest. EBUS "can get the biopsy in 80 percent to 90 percent of cases involving the mediastinum, or the cavity in the center of the chest between the lungs," Dr. Oliveira says. The yield with traditional bronchoscopy would be 50 percent to 60 percent, because the physician cannot always see exactly where the needle is in the chest. "When inserting the needle in a blind way, there have been a very large number of false negatives in the past because we couldn't be sure we got to the lymph node," Dr. Oliveira says. "With the three-dimensional guidance of ultrasound, we can distinguish a blood vessel from a lymph node, and we know for sure the needle is inside the lymph node. I feel very secure about where I'm going because I have a live image to guide me."

Perhaps the greatest benefit of EBUS is that, in many instances, it eliminates the need for a potentially traumatic and unnecessary surgery to determine if a growth is malignant. For cancer patients — or any patient in a weakened state — avoiding additional trauma can also mean avoiding disruption or aggravation of the healing process.

"For someone already undergoing treatment for a lung or thoracic malignancy who is thought to have a recurrence on a lymph node, EBUS is the preferred diagnostic method to determine if this is a recurrence of the malignancy or just an infection on the lymph node," Dr. Oliveira says. "And it's of great advantage because it often allows us to avoid the need for surgery to confirm the diagnosis."

Mr. Stribling compares the procedure to a visit to the dentist. "If they had not been able to use that procedure, they would have had to cut my whole chest open to do the biopsy."

"Instead, I jumped up on the table, they gave me a shot to sedate me, went in through my mouth and windpipe to the bronchial tube, then through the bronchial tube to the tumor," he says. "I woke up, and my throat was not sore. The tumor was, as suspected, malignant, and I went back the following weekend for radiation therapy."

That was the first of 20 radiation treatments Mr. Stribling received over the next five weeks. He and his doctors remain vigilant for recurrences, ready to tackle them as they come.

— ELIZABETH THOMPSON BECKLEY

"With the three-dimensional guidance of ultrasound, we can distinguish a blood vessel from a lymph node, and we know for sure the needle is inside the lymph node." — Eduardo C. Oliveira, M.D.

## Laser therapy cuts tumors down to size

Even after biopsy and diagnosis, tumors in the chest pose a unique set of challenges. They can block a patient's airway, they make swallowing nearly impossible and they can be difficult to remove.

Keith D. Mortman, M.D., treats esophageal and lung cancers in the major airways at Cleveland Clinic in Florida, where he has introduced a new way of combating these complications. The procedure, called photodynamic therapy (PDT), uses a laser to stimulate a light-sensitive dye that kills obstructive cancer cells.

PDT can make tumors easier to remove and helps patients breathe or eat more easily. The light-sensitive dye travels to the site of the cancer, where a laser of a specific wavelength is aimed at it. A chemical reaction kills the tumor cells. The minimally invasive procedure can be performed under sedation on an outpatient basis or under general anesthesia. It's especially useful for patients who have had radiation therapy to their chest and who can't have more because they've received the maximum dosage.

Two to three days before the procedure, the patient receives an injection of porfimer, a photosensitizing agent that remains in cancer cells longer than in normal cells. Using an endoscope or bronchoscope, the doctor inserts the laser into the patient's airway to aim it at the tumor. The reaction produces an active form of oxygen that kills only the malignant cells that contain the dye. Healthy tissue is spared.

"[PDT] usually requires at least two trips to the operating room, where we can start taking out the dead tissue so the patient can breathe better," Dr. Mortman says. "The necrotic, or dead, tumor has a pretty characteristic appearance. After we remove it, if we see there is some underlying viable tumor, then we'll shine that laser light a second time. The patient may need to return to the operating room a third time to have residual tumor removed, this time without the use of the laser."

The whole process can occur within one week, from the day of drug injection to the last trip to the operating room. "Patients usually have a pretty significant improvement to their symptoms, as opposed to the more traditional external-beam radiation and chemotherapies, which take much longer to work and are not without side effects," Dr. Mortman says.

The most common side effect is photosensitivity — the drug can make the skin and eyes especially sensitive to light. Dr. Mortman tells his patients to avoid sun exposure for 30 days. He encourages precautions, such as running errands at night, or, if daytime activities cannot be rescheduled, covering the skin completely with long sleeves and pants, gloves, sunglasses and a hat to reduce the risk of serious sunburn. — ETB

BY BONNIE SANDERS POLIN, PH.D., as told to *Cleveland Clinic Magazine*

# A Cook's Journey

**I had all the classic symptoms of diabetes.** I felt incredibly thirsty, I frequently had to run to the bathroom and my eyesight was sometimes fuzzy. I felt like I was walking through a cloud. I was always exhausted, and these symptoms were affecting my work as a child psychologist at a hospital. It became so bad that sometimes I dozed off in my office.

But what was really surprising was being diagnosed with "juvenile diabetes," now called type 1 diabetes. How could this be happening? I had juvenile diabetes even though I was 41 years old.

Right after the diagnosis in 1983, I felt mostly fine. My body was in the so-called "honeymoon period," when I still had a few healthy cells and didn't need to take insulin. This lasted a couple of years — much longer than normal, the doctors said.

But instead of feeling fortunate for this short reprieve, all I felt was scared, confused and alone. I felt like there was no one to guide me as I tried to make sense of my condition. No one told me to see a nutritionist or a dietician. I tried to control what my body was going through by running up to six miles a day and not eating very much. Before long, I was very sick — and starved.

I ended up in the hospital with a serious viral infection. I was released after two weeks and told it was time to start taking insulin. The shots really hurt at first, but after a while they became routine. I began to feel much better and didn't look like a scarecrow anymore. My eyesight returned to normal, as did my energy level.

But life was not the same. I kept a vigilant eye on my blood sugar and resigned myself to eating the same bland food every day. I thought food was the enemy, and I felt deprived. I missed eating sweets. I felt like no one had figured out how to cook delicious food for people with diabetes, and it got me thinking: Would it be possible to modify recipes so that everyone — diabetes or no diabetes — could enjoy them?

I had always loved cooking and decided to experiment with one of my favorite recipes, a basic genoise sponge cake. I used fructose (which is no longer recommended for people with diabetes because it raises blood sugar) and combined it with a lot of egg whites. After much trial and error, I created a cake that tasted like a cake — a small triumph in an otherwise gloomy situation.

Making that first cake inspired me to do even more. I started reading everything I could get my hands on about what makes a diet friendly for people with diabetes.

With the help of my younger sister, who worked for a book publisher in New York, I decided to write a cookbook for people with diabetes. It took me five years to complete my first book, *The Joslin Diabetes Gourmet Cookbook*. It was one of the first cookbooks for people with diabetes, complete with recipes for gourmet dinners, quick meals and snacks.

For a brief moment, life was good. But unbeknownst to me, my diabetes was silently damaging my heart. I didn't feel the pain until it was too late. And in 1993, I had to undergo open-heart surgery. The surgery was successful, but it left an impression on me: People with heart disease face dietary problems similar to people with diabetes.

So I wrote a cookbook in collaboration with Cleveland Clinic called *Healthy Heart*, which has something in common with the books that came before it. It, too, is about change, and change is difficult. What I found, though, is that change doesn't have to leave you with an unsatisfying taste in your mouth. Instead of taking parts of your life away, change can actually give you something in return. It did for me. And now I get to help others with diabetes and heart disease live healthier, more flavorful lives.

**Bonnie Sanders Polin, Ph.D.**, is a former patient at Cleveland Clinic and the author of four books for people with diabetes and heart disease. Her newest cookbook, co-authored with Frances Towner Giedt, is *Cleveland Clinic Healthy Heart Lifestyle Guide and Cookbook* (Publisher: Broadway 2007). She resides with her husband in Tulsa, Okla.

ERIC HANSON

TODAY'S INNOVATIONS → TOMORROW'S HEALTHCARE

Campaign for Cleveland Clinic

# The future of healthcare is in your hands.

Join the initiative to raise $1.25 billion for

- expanded world-class facilities
- groundbreaking research
- advanced medical education
- compassionate patient care

## Support Cleveland Clinic.

*For information, go to:* ***clevelandclinic.org/giving***
*or call: 216.444.1245 or 800.223.2273 x 41245*

iSupport
*Make a gift online*

Cleveland Clinic

The Cleveland Clinic Foundation
Institutional Relations and Development / DVb
9500 Euclid Avenue, Cleveland, OH 44195

RANKED ONE OF AMERICA'S TOP HOSPITALS

MAILED FROM ZIP CODE 44101

NON-PROFIT ORG.
U.S. POSTAGE
**PAID**
PERMIT NO. 4184