

# Health

## UF cardiologists, surgeons team up to offer life-extending procedure



For patients who have severe narrowing of the aortic valve, a condition known as aortic stenosis, standard treatment is surgical replacement of the damaged valve.

But advanced age or medical problems such as lung disease prevent many of those patients from having open chest surgery.

In the past, the best such patients could hope for was to control their symptoms with medications.

Now they can live longer thanks to a new minimally invasive treatment that involves inserting an artificial

valve that takes over the work of the diseased valve.

The University of Florida is among a limited number of facilities around the country initially approved to offer the procedure.

"It's exciting — this technology opens an option for patients who otherwise do not have a repair option," said cardiologist Dr. Anthony A. Bavry, an assistant professor in the UF College of Medicine's department of medicine.

"Previously we had to treat these patients with medications, and unfor-

tunately many did not do well. This is a big change."

The new valve replacement technique, called transcatheter aortic valve replacement, or TAVR, was approved by the U.S. Food and Drug Administration in November 2011.

Bavry and Dr. R. David Anderson, director of interventional cardiology at UF, will team with thoracic and cardiovascular surgeons Dr. Thomas M. Beaver, and Dr. Charles T. Klodell, to do the procedure at UF&Shands, the University of Florida Academic Health Center. Working in such multidisciplinary teams streamlines and speeds patient evaluation and decisions about the best course of action.

"You have both a surgeon and a cardiologist seeing a patient, reviewing the data and making the best decision about how to treat," Bavry said.

Among the elderly, severe aortic stenosis is the most common abnormality of the heart valves. But up to one-third of such patients are considered ineligible for surgery.

They are instead given medicines to control heart rate and blood pressure, and their heart volume is monitored in order to head off congestive heart failure. Medical treatments ease symptoms but do not prolong life.

In the new TAVR procedure, the artificial valve — framed by a stent and wrapped around a balloon — is transported up to the aortic valve via a large catheter in the leg.

The new valve is then anchored into position inside the diseased valve by inflation of the balloon. Placement of the stent is monitored with X-ray and ultrasound imaging.

Patients' survival chances improve with the new technique. In clinical trials involving 700 patients, treatment with the new procedure cut the death rate nearly in half after one year of having the implanted device, compared with medical therapy alone.

increasing the body's insulin production.

People with type 2 diabetes are unable to properly break down carbohydrates, either because their bodies do not produce enough insulin or because they've become resistant to the hormone, which controls blood sugar levels.

These patients are at higher risk for heart attacks, kidney problems, blindness and other serious complications. Diabetics often require multiple drugs with different mechanisms of action to control their blood sugar levels.

Diabetes affects more than 25 million people in the U.S., or roughly 8 percent of the population.

Amylin executives say the convenience of the Bydureon's weekly regimen should give it a competitive advantage, but Amylin reported disappointing results last year for it against Novo Nordisk's Victoza, a daily injection approved in January 2010.

On average, Bydureon reduced blood sugar levels in diabetics less than Victoza, which uses a different mechanism of action.

A monthly series of Bydureon injections is expected to cost \$323, compared with \$291 for the older Byetta.

## Amylin's long-delayed diabetes drug gets FDA nod

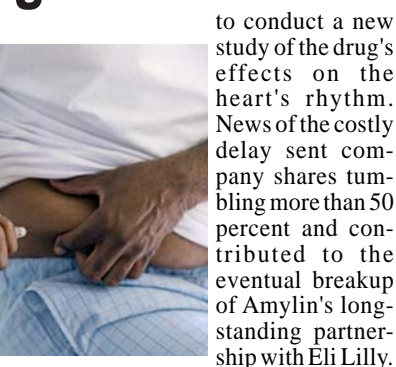
Amylin Pharmaceuticals won approval Friday for its long-delayed diabetes drug Bydureon, a next-generation treatment that requires fewer injections than the company's 7-year old diabetes medicine, Byetta.

Bydureon is a once-a-week version of Byetta, which is taken twice a day to control blood sugar.

Amylin executives say the new drug's convenient regimen will give it a competitive advantage in the marketplace.

However, after multiple delays it enters a crowded market, including one diabetes treatment in the same class that has shown superior results.

The Food and Drug Administration approval comes after two rejections in 2010, when the agency asked Amylin



to conduct a new study of the drug's effects on the heart's rhythm. News of the costly delay sent company shares tumbling more than 50 percent and contributed to the eventual breakup of Amylin's long-standing partnership with Eli Lilly.

The companies ended their collaboration in November, with Amylin paying \$250 million and agreeing to take over full responsibility for both Byetta and Bydureon.

Analysts generally expect Bydureon to generate \$940 million in sales annually by 2016, though Deutsche Bank analyst Robyn Karnauskas says the drug must post \$1.2 billion annually to turn a profit.

Bydureon is part of the broader GLP-1 class of drugs, which work by

## UF researchers develop gene therapy that could correct a common form of blindness

A new gene therapy method developed by University of Florida researchers has the potential to treat a common form of blindness that strikes both youngsters and adults.

The technique works by replacing a malfunctioning gene in the eye with a normal working copy that supplies a protein necessary for light-sensitive cells in the eye to function.

Several complex and costly steps remain before the gene therapy technique can be used in humans, but once at that stage, it has great potential to change lives.

"Imagine that you can't see or can just barely see, and that could be changed to function at some levels so that you could read, navigate, maybe even drive — it would change your life considerably," said study co-author William W. Hauswirth, the Rybczki-Bullard professor of ophthalmology in the UF College of Medicine and a professor and eminent scholar in department of molecular genetics and microbiology and the UF Genetics Institute.

"Providing the gene that's missing is one of the ultimate ways of treating disease and restoring significant visual function."

The researchers tackled a condition called X-linked retinitis pigmentosa, a genetic defect that is passed from mothers to sons. Girls carry the trait, but do not have the kind of vision loss seen among boys. About 100,000 people in the U.S. have a form of retinitis pigmentosa, which is characterized by initial loss of peripheral vision and night vision, which eventually progresses to tunnel vision, then blindness.



"These children often go blind in the second decade of life, which is a very crucial period," said co-author Alfred S. Lewin, a professor in the UF College of Medicine department of molecular genetics and microbiology and a member of the UF Genetics Institute. "This is a compelling reason to try to develop a therapy, because this disease hinders people's ability to fully experience their world."

In some cases, loss of sight coincides with the appearance of dark-colored areas on the usually orange-colored retina.

The UF researchers previously had success pioneering the use of gene therapy in clinical trials to reverse a form of blindness known as Leber's congenital amaurosis. About 5 percent of people who have retinitis pigmentosa have this form, which affects the eye's inner lining.

"That was a great advance, which showed that gene therapy is safe and lasts for years in humans, but this new study has the potential for a bigger impact, because it is treating a form of the disease that affects many more people," said John G. Flannery, a professor of neurobiology at the University of California, Berkeley who is an expert in the design of viruses for delivering replacement genes. Flannery was not involved in the current study.

The X-linked form of retinitis pigmentosa addressed in the new study is the most common, and is caused by degeneration of light-sensitive cells in the eyes known as photoreceptor cells. It starts early in life, so though affected children are often born seeing, they gradually lose their vision.

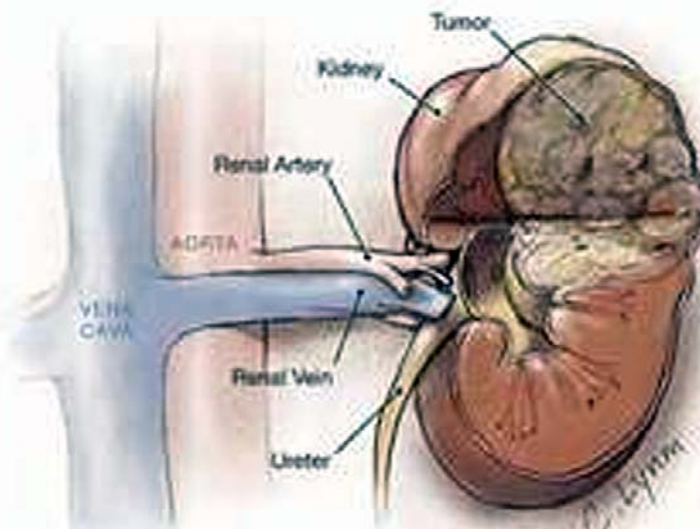
The UF researchers and colleagues at the University of Pennsylvania performed the technically challenging task of cloning a working copy of the affected gene into a virus that served as a delivery vehicle to transport it to the appropriate part of the eye. They also cloned a genetic "switch" that would turn on the gene once it was in place, so it could start producing a protein needed for the damaged eye cells to function.

After laboratory tests proved successful, the researchers expanded their NIH-funded studies and were able to cure animals in which X-linked retinitis pigmentosa occurs naturally.

The injected genes made their way only to the spot where they were needed, and not to any other places in the body. The study gave a good approximation of how the gene therapy might work in humans.

"The results are encouraging and the rescue of the damaged photoreceptor cells is quite convincing," said Flannery, who is on the scientific advisory board of the Foundation Fighting Blindness, which provided some funding for the study. "Since this type of study is often the step before applying a treatment to human patients, showing that it works is critical."

## FDA clears Pfizer drug for advanced kidney cancer



Patients with hard-to-treat kidney cancer that has spread to other parts of the body gained a new drug option Friday, after federal regulators approved a twice-a-day pill from Pfizer for the disease.

The Food and Drug Administration approved the company's drug Inlyta as a secondary option for patients with renal cell carcinoma that hasn't responded to previous drug treatments.

## Ringing in your ears?

Did you ever suffer from an annoying ringing in your ears?

For some it's a temporary annoyance, but for up to 50 million people, that ringing noise doesn't always go away.

The people who hear this incessant ringing suffer from tinnitus, which can also cause patients to hear hissing, chirping or whistling.

Tinnitus is caused by:  
 - Exposure to loud noises  
 - Certain disorders like hypothyroidism and fibromyalgia  
 - Wax build up  
 - Jaw problems  
 - Cardiovascular disease

There is no cure for tinnitus but there are treatment options available such as hearing aides, cochlear implants, and certain medications.

## Researchers find cancer in ancient Egyptian mummy

A professor from American University in Cairo says discovery of prostate cancer in a 2,200-year-old mummy indicates the disease was caused by genetics, not environment. The genetics-environment question is key to understanding cancer. AUC professor Salima Ikram, a member of the team that studied the mummy in Portugal

for two years, said Sunday the mummy was of a man who died in his forties.

She said this was the second oldest known case of prostate cancer.

Living conditions in ancient times were very different; there were no pollutants or modified foods. The oldest known case came from a 2,700-year-old skeleton of a king in Russia.

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