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A less-open heart surgery

The new valve is placed via a small cut, not a cracked chest.

By Josh Goldstein

Inquirer Staff Writer

Ralph Miller's heart is failing. Without a new aortic valve, the 70-year-old retired railroad worker from Chester County will likely die within two years.

But an experimental procedure performed yesterday at the Hospital of the University of Pennsylvania replaced Miller's diseased valve without risky open-heart surgery.

"I won the lottery," Miller said. "I never won a damn thing in my life."

Miller's care could represent a new trend in heart-valve surgery. Patients now get their chests cracked open for valves to be replaced. In Miller's case, a surgical team made a small incision in his chest and threaded a new valve in through an artery and placed it inside his heart.

The treatment, already approved in Europe, could help thousands of people like Miller who are too sick to survive the rigors of open-heart surgery.

"This is going to be a paradigm shift in how we treat" heart-valve patients, predicted interventional cardiologist Howard C. Herrmann, who co-led the operation yesterday.

Still, the procedure is not yet approved by the Food and Drug Administration, and other surgeons have different ideas about how future valve surgery will be conducted.

An estimated 57,000 aortic valve replacements were done in 2006, according to an Inquirer analysis of the National Hospital Discharge Survey. That compares with 444,000 who got bypass surgery that year.

About 3 percent of patients undergoing traditional valve procedures die, but that rate jumps to 8 percent or higher for patients in their 80s and 90s, doctors say.

Yesterday afternoon, Miller, nicknamed Fuzzy when he started at the Pennsylvania Railroad as a 17-year-old in 1955, was wheeled into a "hybrid" operating room at Penn for the 35-minute procedure.

He was the 19th patient to undergo this experimental valve replacement at Penn, the only area hospital participating in a national trial of the device and procedure.

"This is radical, revolutionary surgery," said Joseph E. Bavaria, a heart surgeon who performed

Miller's operation along with Herrmann, an expert at unplugging clogged arteries with wire mesh devices called stents.

The new procedure requires the expertise of both kinds of doctors.

"I think joint programs are going to be the key," Herrmann said. "Both specialties will have something to offer here."

The valve, made of cow tissue, is housed in a stent. The entire device is collapsed around a balloon and a guide wire.

Most of these operations are started through an incision in the groin, but Miller's blood vessels were too small to permit that. So the device was inserted through his chest and then put inside the diseased valve.

The balloon was then inflated, pushing the diseased tissue back against the arterial walls.

The Sapien device, made by Edwards Lifesciences Corp. of Irvine, Calif., costs about \$28,000 in Europe, or about five times a traditional, surgically implanted valve. Prices here have not yet been established.

The company, which is underwriting the trial, called PARTNER, paid Bavaria \$5,000 for teaching a class for fellow doctors, a Penn spokesman said, while Herrmann received no money.

At the moment, the sickest valve patients have few options.

"There are many high-risk patients who are not being referred for surgery" because of the fear they might not survive the operation, Herrmann said.

Opening the diseased valve with a balloon - valvuloplasty - provides only temporary relief. The new procedure could shorten recovery time.

"We are being swamped with requests from patients," Bavaria said.

But there are risks.

Because the new device pushes back the diseased valve, the uneven surface can cause leaks. The device also can cause punctures or tears to the blood vessels en route to the heart.

And an improperly placed valve can get loose in the aorta, a life-threatening complication.

Still, many heart surgeons and cardiologists believe the new devices will become easier to use, and will overtake the traditional surgery just as angioplasty and stents have supplanted heart bypasses.

"I personally think it is something that is going to grow and become more widespread after these trials," said Lynn B. McGrath, chairman of cardiothoracic surgery at Deborah Heart & Lung Center in Burlington County, N.J., who is not involved in the research.

As a result, the number of heart surgeries at some area hospitals could continue to decline, raising concerns about safety and quality since high surgical volumes are often associated with good results.

"I think it is a nail in the volume coffin," McGrath said. "There are programs now in Pennsylvania and in New Jersey that, because of the falling bypass volumes, are surviving on aortic valve surgery. You

need to have certain critical volume in order to maintain your skill sets."

Policymakers must wrestle with how to maintain quality as this technology becomes more widely available.

Other device-makers are working on developing their own valves. And a heart surgeon at the University of Maryland Medical Center in Baltimore says he thinks that bypassing the diseased valve could be a better way to go.

In the journal *Circulation* last month, surgeon James S. Gammie reported that using a new valve embedded in a bypass graft "reliably relieves aortic stenosis," or narrowing of the valve.

Gammie said he did not need FDA approval because he was using approved devices.

Yesterday morning, before his surgery at Penn, Miller was joking around with his three children and his wife. He was happy that the day had finally arrived, and hoped that he could soon be able to return to his barn near Longwood Gardens where he rebuilds tractors.

He wants to play with his eight grandchildren without having to catch his breath.

"They tell me as quick as I get this thing in me, I'll be able to breathe well again," he said.

Yesterday evening, Bavaria reported, the surgery had gone well, with no complications so far.

Contact staff writer Josh Goldstein at 215-854-4733 or jgoldstein@phillynews.com.

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