A mother's heart

New-generation cardiac devices promise not just to extend but to improve lives

by MICHAEL FINLEY
for *Twin Cities Business Monthly*

I have a favorite picture of my mother, Mary Mulligan Konik, from 1936 when she was in the seventh grade. The expression I see in her eyes is like she is waiting for something wonderful to happen. I know from visiting her family farm in Michigan as late as the 1960s that she grew up without running water, indoor plumbing, gas or electricity. They got a phone -- the Mulligans' one concession to modernity -- in the 1940s.

But for the last eight years of her life, her heart was maintained by a series of internally embedded cardiac pacemakers made by Medtronic and Guidant, each one more advanced than the one before.

It was a quite a century, and my mother, a kind of amateur historian, appreciated the advances that she saw.

Setting the pace

Pacemakers don't ask why your heart has broken – in my mother's case the result of diabetic neuropathy, the death of a husband, and a rising creek that entered her home and ruined much of what she treasured in life. Her first heart attack (of four) followed weeks later.

Sidebar:

The four-chambered heart

The heart is a house of four rooms. The top two rooms are called the *atria*, and the lower two the *ventricles*. During a heartbeat, the atria contract to force blood into the ventricles below, and the ventricles push that blood out into the body.

Healthy hearts pump about 5 liters of blood trough the body every minute, through a "fist-making" pattern of relaxation and contraction of the heart walls. The heart naturally performs this life-refreshing, synchronous rhythm about 70 beats per minute.

What implanted pacemakers do is supplement the natural pacemaking work of the heart. The body's "natural pacemaker" is a small mass of specialized cells named the sinoatrial node, located at the top of the right atrium. Signals from this node travel through the atria and cause them to contract, sending blood on to the ventricles.

When my mother had her first heart attack, the tissue of her heart was permanently damaged, and the sinatrial node with it. The damage was such that she was only able to pump out 15% of a "heartload" of blood into her arteries with each beat. She was like a motor out of tune, unable to do much more than scribble a few lines and drift back to sleep.

Sidebar:

Pacemaker basics

A cardiac pacing system consists of three parts:

- A generator. About the size of a cigarette case, smooth, lightweight case containing a tiny computer and a battery.
- The connector or header. What the leads plug into.
- The leads. Wires coated with soft, flexible plastic that are surgically attached to the heart walls.

The pacemakers my mother had had two leads, connecting to her right atrium and right ventricle. They kept the heart beating satisfactorily but not strongly -- not in the synchronous rhythm of a healthy heart. Even with her pacemakers (which were replaced every couple of years to refresh the battery or include a defibrillator unit to shock the stopped heart into restarting) her final years were limited by low energy, lightheadedness, shortness of breath, and the pooling of fluids in her extremities – classic symptoms of congestive heart failure.

On the one hand, her life was a medical miracle, especially for a farm girl from Michigan. She remained sentient and alive because of a raft of medications and her pacemaker. This allowed her to pursue her fascination in life – conducting genealogical research by mail. But stooping to pick up a dropped envelope could be a tremendous adventure. As methodically as she bent, and as gradually as she moved, she still had to steady herself on a chair arm. How often she fell and kept her mouth shut about falling, I can't tell you.

A hitch in the giddyup

To address this energy shortcoming, Guidant and Medtronic, the Lou Gehrig and Babe Ruth of cardiac devices worldwide, respectively, each with major operational facilities here in the Twin Cities, developed a new kind of pacemaking called biventricular pacing. This was not an incremental improvement to an existing product but a whole new approach, costing nearly a billion research dollars.

Sidebar:

Symptoms of heart failure

- Dyspnea -- shortness of breath

- Difficulty breathing when lying down
- Edema -- swelling of the legs, ankles, and feet
- General fatigue and weakness
- Mild confusion

Source: Medtronic.com

Instead of the customary two leads to the heart wall, biventricular pacing (also called cardiac resynchronization therapy or CRT) connects to three points to coordinate ("synchronize") the contractions of the left and right ventricles. This improves the efficiency of blood being pushed out, which means more power from even a damaged heart.

Long-term results from biventricular pacing is not yet available. It has not been definitively proven that the new approach lengthens lives beyond what previous-generation devices did (although, unofficially, the people at Guidant and Medtronic are very bullish on the approach).

But studies are conclusive on other points. Resynchronizing the heartbeat definitely makes a weak heart stronger, so patients have more energy to do the things they want to do. That trip to the store that was too agonizing to watch, or too much trouble to take, is no longer out of the question. Exercise, which heart patients need to do to maintain mobility and muscle tone, is no longer a faustian bargain, necessary but impossible.

"We are able to offer demonstrable improvement not just in quantity of life but in quality of life," said Joe Smith, chief medical director at Guidant. Smith is himself a practicing electrophysiologist, so he is not shut away from the everyday problems of people in heart failure – he sees the benefits of biventricular pacing every day.

"Every year we lose 450,000 people to sudden death, people like Bret Favre's father, who died suddenly just before the last Superbowl," Smith said. "In all, five million people die of heart failure yearly, with another 500,000 diagnosed. Until now all we could do was identify people at risk, and fit them with devices that kept them from dying. Now we have the capability of restoring people to their lives."

The procedure is not entirely without risk. Implantation has been known to set off an uncontrollable, abnormal heart rhythm (ventricular tachycardia or fibrillation). But the promise of cardiac resynchronization, says Dr. Andrew Boyle, professor of cardiology at the University of Minnesota in Minneapolis, "is that a lot more people will live a lot longer, and in better health. It will take a load off heart transplantation, which is limited by the number of available hearts."

The face in the photo

I think my mother might have been a candidate for biventricular pacing. Possibly not – she was a Type 1 diabetic and she was 79 years old. But I would have given anything to see her get her wind back even for a short time, and hear her voice again in full, instead of the whisper she was reduced to.

I find meaning in the fact that she died on her favorite day of the year, the feast of Saint Patrick. She was a wearer of the green in sunshine and in shadow. And I remember one day, when we were out on one of our aimless drives in and around Saint Paul, she grabbed my wrist and pointed out the window.

It was the Guidant campus in Arden Hills. She recognized the name on the sign, and she knew the company had enabled her to pursue her genealogical work for a few more years, and to teach a great-grandson how to read.

And the faraway look on her face was the same as in the photograph, all those years before.

Sidebar:

Picking up the pace

If you're an investor, should biventricular pacing make your heart quicken?

Minnesota is the home of the two big players in CRT technology, Medtronic (MDT) and Guidant (GDT). And a third player, St. Jude Medical (STJ) is waiting for FDA approval of its biventricular pacing product.

We asked Piper Jaffray's biomedical stock analyst Tom Gunderson to sort the three out.

- First, the opportunity is real. "The CRT-D devices doubled growth in the sector and they enjoy higher margins than earlier products. Altogether, they have added at least a billion dollars of incremental revenues to the MDT and GDT coffers."
- Of two companies, Guidant, because it is smaller ad less diversified, stands to gain more from the products' success. "An extra quarter of a billion dollars has a greater impact to Guidant's bottom line." Eventually, look to St. Jude Medical to nap a 20% share of this market.
- It's too late to get in at the bottom. "The surprise upside in revenues and earnings was last year." But cheer up, all three are still "well-run businesses with solid product lines."

Sources

- Thomas Gunderson, Managing Director, Senior Research Analyst, Health Care, Piper Jaffray, (612) 303-6467, 800 333-6000
- Andrew Boyle, MD, University of Minnesota, 612-624-4693, boyle033@umn.edu
- Joe Smith, Chief Medical Officer, Guidant, 651-582-9040