Boomers' embrace of devices gives rise to new med-tech age

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Jay Alva's sneakers pounded the treadmill, set to the speed of a brisk walk. Sweat dripped off the 53-year-old as he hit a groove during a recent workout.

For almost two decades, the youth soccer and football coach from Eagan, Minn., moved like a man who needed a walker. A degenerative hip condition prevented Alva from running with his players or even doing basic things like tying his shoes.

Brushing off a doctor's advice that he was "too young," Alva got artificial hips four years ago. Now pain-free, he moves with the energy of a man in his 30s, amused at the notion that he wasn't old enough for such treatment.

"I am living so much better now in my 50s than I did in my 40s," Alva said.

Hundreds of thousands of Americans are receiving medical devices that were once considered nearly exclusive to the elderly. The shift is profoundly changing patient care and expanding the fortunes of the medical-technology industry while amplifying concerns over the safety and oversight of some products.

The movement is so dramatic that the futures of major medical device companies such as Medtronic, St. Jude Medical and Boston Scientific are increasingly tied to younger groups and the new markets they

represent.

Middle-age Americans, in particular, are driving this trend as they seek ways to remain physically active. The number of patients ages 45 to 64 who had a hip replacement more than doubled from 2000 to 2010, according to a Star Tribune analysis of data from the U.S. Department of Health and Human Services. The increase was more pronounced for knee replacements, rising 213 percent.

"This is huge," said Dr. Robert Hauser, a cardiologist at the Minneapolis Heart Institute who has studied the safety and effectiveness of heart devices for years. "I think it's a tremendous step forward, but there are issues that need to be dealt with."

Though widely celebrated, some treatments have been shadowed by reports of devices or other medical products faltering - defective wires in defibrillators, failing artificial hips and leaky drug pumps, among them. Patients have suffered complications, severe pain and even death. Every year, 25 to 40 medical devices are recalled for high risk - meaning a patient's life could be in jeopardy.

Device companies are facing thousands of patient lawsuits challenging the safety of some devices, and federal regulators are under greater pressure to intensify their oversight. At the same time, device makers are spending millions to promote their products to doctors and patients while simultaneously pushing to simplify governmental reviews to quicken their products' path to market.

Doctors and device makers are converting technology to regulate heart rhythms or treat diabetes into new tools for a wider range of ailments, including overactive bladders, anxiety and migraines. The result is a wider range of devices and other medical products being implanted or connected to more nonelderly patients.

But this growing use of medical hardware should be tempered by a call for safety, public disclosure and caution, consumer advocates say.

"We're not talking about computers or cars or toasters," said Lisa McGiffert, director of the Consumers Union's Safe Patient Project, a group that campaigns for better medical practices. "We're talking about things that go inside people's bodies."

No area of medicine is seeing more nonelderly patients turn to medical devices than orthopedics.

In 2000, one-third of the estimated 157,000 Americans who had hip or knee replacements were younger than 65. Ten years later, the number had nearly tripled to 430,000, meaning almost half of those procedures were performed on these younger patients.

Two contradicting forces are pushing patients toward artificial joints. The rising rate of obesity has led to more cases of deteriorating hips and knees from excess weight. And yet, more Americans are playing sports or exercising in their 30s, 40s and 50s, which puts more wear and tear on their joints.

To get active again - and quickly - patients are more willing to consider joint replacement at a younger age than they were a decade ago, said Dr. Daniel Berry, chairman of orthopedic surgery at the Mayo Clinic in Rochester, Minn.

"We're seeing higher demand," Berry said of younger patients who want a new hip. "And they are going to use it a lot harder than somebody who is older."

Patients who get a device at a younger age usually must replace it more often. Each replacement means an expensive surgery, possible

complications and significant rehabilitation.

"You have to find a happy medium," Berry said. "Think about it like the tires on your car. There's no point in getting new tires if you're not driving ... but if you speed up, they wear out faster."

Medical device companies are working to create joints that are more durable and feel more like the original. Stryker, an international medical device company based in Michigan, had younger customers in mind when it developed hip and knee products that have more natural range in motion, said Joe Cooper, Stryker's director of global communications.

"Designing implants that return this active and high-demand patient population to their lifestyles and everyday activities is a priority," he said.

TGS Knee Innovations, a startup device company in Plymouth, Minn., created a partial-knee replacement system that is designed to be a good option for younger patients facing a knee replacement, said Wesley Johnson, the company's co-founder.

TGS has a relatively "small footprint" in the orthopedic field, but Johnson sees a future filled with youthful patients who want new knees to do more than they did before.

"For orthopedics, that tidal wave is a broader patient population with higher expectations," he said.

Most artificial hips have a life span of 15 to 20 years, depending on how much patients weigh and how hard they push their bodies. Some companies developed a hip that used all-metal components in the belief it would improve durability. It didn't necessarily turn out that way.

Many patients reported problems that have included loosening of the hip, dislocation and metal particles circulating in the bloodstream. They question whether the U.S. Food and Drug Administration, which has oversight of medical devices, adequately scrutinized the devices before approval.

Terri Wagner-Morley of St. Paul, Minn., had what is commonly referred to as a metal-on-metal hip - produced by DePuy Orthopedics Inc. - implanted in 2008. Within two years, the hip began "popping." Soon, the pop turned to pain.

Wagner-Morley had the hip removed, but infection prevented doctors from putting in a new one. Plastic "spacers" were implanted instead, and she was bedridden. Last summer, she had a metal and ceramic hip implanted, but a stress fracture during rehabilitation has left the 55-year-old woman limping and angry. She remains disabled and without a job.

"I have had four surgeries now," Wagner-Morley said. "As I get older, I'm probably going to be wheelchair bound. I might have a positive view, but really, I'm pissed off."

In 2010, DePuy recalled the hip that had been implanted in Wagner-Morley.

That same year, hospitals, patients and med-tech companies reported 230,000 adverse events involving medical devices. About 30,000 of those incidents resulted in hospitalization, according to an analysis by DeviceMatters, a company which interprets data on medical devices.

"You've got to get this right - or people are going to suffer," said Hauser, who discovered flaws in the wires of some defibrillators that led to a major recall.

Alva said he doesn't worry about complications or the durability of his new hips. Being able to pace the sideline of his son's games, ride a bike or refinish his floors overrides such concerns.

"When I need (new hips) again, I'm confident the technology will be better," Alva said. "How can it not be?"

Minnesota's med-tech giants - Medtronic, St. Jude Medical and Boston Scientific - have generated billions in sales in the past 15 years through the development of devices and technology designed to keep the heart beating in aging patients.

Now they are expanding those innovations to treat a variety of other ailments, many afflicting patients who haven't reached their golden years.

Brent Peterson, a former professional hockey player and coach who lives in Nashville, Tenn., relies on a small, pacemaker-like gadget to calm his Parkinson's symptoms by sending a stream of electricity to a spot deep within his brain.

The 55-year-old is a special adviser to the Nashville Predators of the National Hockey League. He learned that he had Parkinson's disease more than a decade ago. At one point, he was taking 25 pills a day.

When Peterson's device was implanted in 2011, his hands immediately relaxed, and his movements steadied. "The day they turned it on, I knew I didn't want to be without it ever again," he said.

Medical device makers didn't set out to adapt pacemakers to treat other parts of the body, but it made sense to expand the technology as doctors explored what else could be treated with an electrical pulse, said Martin Gerber, senior research and development director at Medtronic.

Peterson's device, a Medtronic Activa neurostimulator, can be programmed and adjusted to change as his symptoms evolve. More than 100,000 patients worldwide have received Medtronic's deep-brain stimulation therapy.

The treatment is part of what is called neuromodulation. Implanted devices are used to send medication or electrical pulses into the brain or to the spine to block pain, relax overactive bladders by targeting nerves near the tailbone or ease chronic migraines at the base of the skull. Researchers are exploring electrical stimulation to treat epilepsy, obsessive-compulsive disorder and severe depression for those who have not responded to medication.

The emerging innovations are expanding the products and profits for medical device makers.

At Fridley, Minn.-based Medtronic, the world's largest medical-technology company, nearly half of its $16 billion in revenues last fiscal year came from treating something other than the heart, its core market. And at St. Jude Medical, based in Little Canada, Minn., officials expect sales from the company's nonheart rhythm products to surpass the heart rhythm business this year.

Med-tech executives say they are not specifically targeting young patients with these technologies. But they acknowledge these new treatments are attracting younger patients.

"It's a tremendous growth opportunity," St. Jude Medical Executive Vice President John Heinmiller said. "How can we innovate those technologies to attack these expensive epidemic diseases that are out there? We are looking at investments that treat a broad patient population."

Most patients - more than 14,000 estimated in 2010 - who turn to spinal, brain or other stimulation devices are well below retirement age. Of those patients who had a spinal cord stimulator implanted, an estimated 69 percent were younger than 64, with more than 21 percent between the ages of 18 and 44.

Dr. Mehul J. Desai, director of spine, pain medicine and research at Metro Orthopedics & Sports Therapy in Silver Spring, Md., believes the numbers will continue to climb.

"There has been a push by clinicians to think about these therapies earlier on," he said.

Medical device makers invest heavily to promote their devices to doctors, health organizations and patients.

The average marketing budget for companies of various sizes was $14.4 million in 2013, according to a survey of medical device executives by Medical Marketing & Media.

Most of those funds will not be spent on consumer education, according to the marketing survey. Instead, promotional budgets will focus on persuading health care professionals to use a particular brand of device on their patients.

Medtronic's advertising and promotional spending in 2012 exceeded $128 million, according to Carol Greenhut, president of Schonfeld & Associates, which produces reports on medical device marketing for clients. That same year, Greenhut said, St. Jude Medical spent nearly $45 million and Boston Scientific $20 million.

Medtronic and Boston Scientific declined to confirm those figures, offer their own or discuss their marketing strategies. A St. Jude spokeswoman

said Schonfeld & Associates' figure "significantly overestimates our advertising and marketing expenses," but she declined to provide an alternative.

Advocates for more extensive testing say device makers' promotional emphasis remains on sales, not safety.

"One thing is obvious: They spend a lot more on advertising and lobbying than they spend on testing," said Diana Zuckerman, president of the National Research Center for Women & Families.

But it remains unclear whether corporate marketing is driving the expanded use of medical devices. Certainly, more doctors are willing to consider them before other options have been exhausted.

In many cases, doctors remain hesitant because they simply don't know how long a device will last and under what conditions, said Joseph Galatowitsch, president of Dymedex, a consulting firm that works with medical technology companies.

"The tension is that clinicians want to use these technologies in younger patients," Galatowitsch said. "But they feel frustrated because they feel forced into weighing the risk versus the benefit."

In the spine business, where many patients begin experiencing pain in their 40s and 50s, Medtronic is seeing a growing demand for more options, depending on their activity, said Rob Fredericks, vice president of global marketing, R&D and strategy for Medtronic Spinal.

For some, the stability of spinal fusion, in which vertebrae are fused together to relieve back pain after a disc has been damaged, might be the way to go. For others who seek greater range of motion, artificial discs may be the best option.

"They want to get back on their feet, back to work, back to activity - more quickly," Fredericks said. Doctors say a patient's age - and how the patient intends to spend his or her remaining years - weighs heavily over the decision to implant a device.

For Doug McConnell, that meant finding a way back into the water. The 55-year-old from Barrington, Ill., is an open water swimmer, swimming hours at a time through tough waves and inclement weather. So, when he suffered two herniated discs in his neck in late 2009, he wanted alternatives to the lengthy downtime and loss of mobility from spinal fusion.

"Quite apart from swimming, I wanted to be able to stay active - work in the garden and play catch with the kids," he said. Then a Chicago physician suggested he try "this whiz-bang thing from Medtronic."

An artificial cervical disc - the Prestige - was implanted. Six weeks after surgery, McConnell was back in the water. Eight weeks after that, he finished a 10-kilometer race.

A year after surgery, McConnell swam across the English Channel.

"It never occurs to us that we have to dial back our activities or interests," he said. "We can anticipate living a lot longer than our parents ... and we want to be able to take advantage of that."

Peter Quimby of Plymouth likes to say that he's "the healthiest dying person you'll ever know."

Quimby is waiting for a heart transplant. He received an implanted defibrillator and a left ventricular assist device in 2011 to help his weakened heart pump blood. Doctors told him not to overexert himself - don't run, just shuffle.

To hell with that, Quimby says. The former paratrooper and college baseball player who graduated from West Point uses the devices to get in a good workout - and prove a point.

Six days a week, he sweats through intense workouts. He teaches a spinning class at the Andover, Minn., YMCA. Recently, he finished the Minneapolis Duathlon, which combines a 15-kilometer bike race with two 5K runs - all while wearing a cumbersome device with wires that extend from his abdomen and batteries tucked into a shoulder holster.

Nobody knows whether the devices will hold up. Quimby said he won't stop. "You didn't give me a life," he tells doctors and device makers. "You gave me my life."

Federal regulators say their primary mission is to determine whether a technology is safe and saves lives - not address longevity or durability, said Christy Foreman, who directs the Office of Device Evaluation in the Center for Devices and Radiological Health at the Food and Drug Administration.

"The pacemakers that we had in 1976 were often times implanted in the abdomen because they were so big. And their battery didn't last as long," Foreman said. "We wouldn't say no to the pacemaker ... because we thought it was too big or didn't last the entire patient life because we know that it is lifesaving technology. So we have to review it for what it is."

The FDA also doesn't regulate how physicians use medical devices. By law, doctors are allowed to use devices in any way they think will benefit their patients, even if the FDA never approved or cleared the device for that purpose.

Ralph Hall, a University of Minnesota law professor who has worked as

a liaison between medical technology companies and the FDA, said the current regulatory approach will have to change as the trend toward younger patients builds momentum. It may not have been critical to assess how long a device would last in an older patient population, he said, but a wave of younger patients requires new ways of determining the life span of devices. The marketplace will demand it.

"This is going to require changes in testing methodology - less on human clinical study and more on bench testing and computer simulations and other types of tools assessing long-term performance," Hall said.

Ultimately, it is up to the patient to decide whether to follow a doctor's orders or the manufacturer's recommended ways to use the device.

Dr. David Feldman, Quimby's cardiologist, is seeing more young patients who need heart devices. Many want a treatment that will last forever.

Feldman explains that medical devices don't work that way.

"What electronic piece of equipment that you buy now do you expect to last more than five years?"

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ELDERLY STILL HOLD MED-TECH MARKET POWER:

Medtronic CEO Omar Ishrak was recently asked about how patients younger than retirement age are becoming more important to the future of the medical technology industry. Ishrak wasn't ready to draw such distinctions.

"All of our patients are important to our future," he said. "The vast

majority of what we do is for Medicare patients."

Most med-tech executives acknowledge that a rising number of nonelderly patients are turning to medical devices as treatments expand for a variety of ailments. But the elderly market remains critical for med-tech firms.

Medtronic makes more than half its revenues from heart rhythm and cardiovascular devices. Three-quarters of those receiving pacemakers and defibrillators are older than 65. That is unlikely to change much as heart disease hits aging Americans.

But device use among different age groups is shifting. In 2000, for example, an estimated 67 percent of all knee replacements were performed on patients 65 and older. By 2010, only 56 percent were elderly.

The Advanced Medical Technology Association, or AdvaMed, the industry's leading trade group, expects the elderly market to expand as baby boomers enter their senior years. "The number of people over 65 is going to increase in the next 20 years," said David Nexon, AdvaMed's senior executive vice president.

AdvaMed also predicts "explosive growth" in international sales as a middle class capable of purchasing orthopedic, cardiovascular and other products expands in India, China and Brazil.

Even the critical issue of device durability is not just a concern of the young, said Dr. Kenneth Stein, senior vice president and chief medical officer for Boston Scientific's Cardiac Rhythm Management Division.

"Patients who are older are living much longer. Even within the Medicare population, defibrillator recipients will live eight, 10, 12 years

after they get their implant," he said. "In the early days ... we never thought patients would outlive their first device."