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Doctors Getting Rich With Fusion Surgery Debunked by Studies

By Peter Waldman and David Armstrong - Dec 30, 2010

Suffering from an aching back, truck driver Mikel Hehn went to see surgeon Jeffrey Gerdes in 2008. The St. Cloud, Minnesota, doctor diagnosed spinal disc degeneration, commonly treated with physical therapy, and said surgery wasn't called for.

Unhappy with the answer, Hehn turned to Ensor Transfeldt, a surgeon at [Twin Cities Spine Center](#) in Minneapolis. Transfeldt performed fusion surgery on Hehn, screwing together three vertebrae in his lower spine.

Fusion aims to limit painful spine movements. This one didn't work out. Two years later, the pain in Hehn's neck, lower back, buttocks and thighs is so bad that he can't hold a job and seldom leaves home, he said in an interview.

"There's days when I just can't take it and the tears run," said Hehn, 52, who lives in Sartell, Minnesota. He said he takes oxycodone for pain, Soma to sleep, [Lexapro](#) for depression and Imitrex for headaches.

Hehn's surgery generated a \$135,786 bill from Abbott Northwestern Hospital in Minneapolis, feeding a national boom in costly fusion surgeries. It also illustrates how spine surgeons have prospered from performing fusions, which studies have found to be no better for common back pain than physical therapy is -- and a lot more dangerous.

The number of fusions at U.S. hospitals doubled to 413,000 between 2002 and 2008, generating \$34 billion in bills, data from the federal [Healthcare Cost and Utilization Project](#) show. The number of the surgeries will rise to 453,300 this year, according to Millennium Research Group of Toronto.

Unnecessary Surgeries

The possibility that many of these and other surgeries are needless has gotten little attention in the debate over U.S. health care costs, which rose 6 percent last year to \$2.47 trillion. Unnecessary surgeries cost at least \$150 billion a year, according to John Birkmeyer, director of the Center for Healthcare Outcomes & Policy at the University of Michigan.

"It's amazing how much evidence there is that fusions don't work, yet surgeons do them anyway," said

Sohail Mirza, a spine surgeon who chairs the Department of Orthopaedics at Dartmouth Medical School in Hanover, New Hampshire. “The only one who isn’t benefitting from the equation is the patient.”

The Twin Cities Spine bill for Hehn’s surgery was \$19,292, his medical records show. The firm received \$8,978 after an insurance discount, \$7,742 of it for Transfeldt’s services. Hehn’s insurer paid after his [bid](#) for workers’ compensation coverage was denied on grounds he wasn’t injured on the job.

Royalties, Consulting Fees

Another beneficiary was [Medtronic Inc.](#), which makes products for spinal surgery, including Infuse, a bone-growing material widely used in fusions. Infuse accounted for \$17,575 of Abbott Northwestern’s charges, Hehn’s medical bills and insurance records show.

Infuse, approved by the U.S. Food and Drug Administration in 2002, had sales of \$840 million last year.

Medtronic paid six of the 10 Twin Cities Spine surgeons -- including Transfeldt -- \$1.75 million in royalties and consulting fees in the first nine months of this year. It also makes other financial contributions to the firm.

“Product usage is not a part of any development or consulting relationship” between Medtronic and doctors, said Brian Henry, a company spokesman.

Eleven Twin Cities Spine fusion patients, most of whom tried to get or hold onto coverage benefits through the Minnesota Workers’ Compensation Court of Appeals, said in interviews that the surgery did nothing to relieve their back pain, and in several cases left them worse off than before.

Hooked on Morphine

The patients illustrate the costs and risks of fusion surgery. They are not a scientifically representative sample of Twin Cities Spine patients, the majority of whom the firm says are happy with the treatment they receive.

One of the 11 died of a methadone overdose when his pain worsened after surgery and he couldn’t afford prescription painkillers, his mother said. Another patient said he is hooked on morphine to ease the burning sensation in his back where screws and rods were implanted in an operation that cost his insurer \$60,000.

Twin Cities Spine performs fusions on patients with conditions the surgery doesn’t treat effectively, said Brian Nelson, an orthopedic surgeon and medical director of a Minneapolis clinic that [stresses](#) exercise for back pain. Nelson said he used to perform fusions and has been in the operating room with at least three of the 10 Twin Cities Spine surgeons.

“I have a lot of respect” for the practice and its surgical skills, Nelson said. “But we have a fundamental disagreement. I think there are too many people being fused.”

Risk Warnings

Payments by medical-device makers pose an “irresistible” temptation to tailor treatment to more-lucrative procedures, said Eugene Carragee, chief of spine surgery at Stanford University in Palo Alto, California. “There is precious little in human nature to suggest this proposition is unlikely.”

Twin Cities Spine believes in a “conservative course of treatment in the vast majority of cases,” according to an e- mailed statement from Lisa Arrington, the practice’s marketing director. There are some people for whom surgery is appropriate, she wrote, and numerous patients “have experienced successful outcomes from spinal fusion procedures,” regaining functionality. The operations “reduced pain and improved their quality of life,” she said.

The firm declined to comment on individual patients, and did not make the doctors who treated them available for comment. Twin Cities Spine surgeons routinely warn of potential surgical risks, including nerve damage, blood clots and the need for more surgery, according to letters provided by several patients.

Degenerative Disc Disease

Financial relationships with medical companies are disclosed to patients and do not influence whether surgery is performed, according to the statement from Arrington. Royalties are not received by Twin Cities Spine doctors on devices they use in surgery, the e-mail said.

Fusion has helped spine surgeons become the best paid doctors in the U.S. Their average annual salary is \$806,000, more than three times the earnings of a pediatrician, according to the [American Medical Group Association](#), a trade organization for doctor practices.

One of the most common causes of back pain is degenerative disc disease, or the breakdown in the soft, puck-shaped cushions between the vertebrae. Pain also comes from a condition called stenosis, or the narrowing of the spinal canal, which can be caused by bulging discs or arthritis.

Narcotics For Pain

British and Norwegian researchers found fusion no better than physical therapy for disc-related pain in three studies, totaling 473 patients, published in the journals *Spine*, *Pain* and the *British Medical Journal* between 2003 and 2006. A 2001 Swedish study of 294 patients in *Spine* found fusion better than physical therapy that was less structured than the kinds used in the other studies.

Rates of complications from surgery in three of the European studies -- including bleeding, blood clots, and infections -- were as high as 18 percent. None reported complications from physical therapy. The

four studies are cited in journals as the only head-to-head, randomized comparisons between the two treatments.

In a U.S. study in *Spine* in 2007, surgeons reported fusion was successful in only 41 percent of 75 patients suffering from lower-back disc degeneration. Success measures included pain reduction. Two years earlier in the same journal, surgeons found a 47 percent success rate among 99 patients, 80 percent of which were taking narcotics for pain two years later. Both studies compared fusion to artificial disc replacement in trials submitted to the FDA.

Evidence 'Lacking'

Evidence that fusion is better than a simpler procedure called decompression for stenosis is "lacking," a study in the *Journal of the American Medical Association* found earlier this year. The study also found that fast-growing complex fusions -- those joining more than three vertebrae -- carried a 5.6 percent risk of life threatening complications, more than double the 2.3 percent rate for decompression, which usually involves cutting away damaged discs or bone pressing on spinal nerves.

Twin Cities Spine performs 3,000 spine surgeries a year, 1,300 of them fusions, and accounts for 75 percent of the spine operations at [Abbott Northwestern](#), according to Daryll Dykes, a surgeon in the practice. More than 4,000 spine procedures a year are performed at Abbott Northwestern, the most of any U.S. hospital, according to its website.

The practice generates big bills. Medica Health Plans, one of Minnesota's largest insurers, says it pays a median of \$26,021 for back surgeries performed by Twin Cities Spine, including hospital and doctor fees. The medians range between \$12,814 and \$23,546 for all other spine and orthopedic practices in the area, Medica says.

Porsches, Ferrari, Mercedes

One Twin Cities Spine surgeon, Manuel Pinto, 56, earned \$1.85 million from the practice in 2007, according to filings in his divorce proceedings that year. He told state superior court in Minneapolis that he and his wife's assets included two Porsches; a Ferrari 430 coupe; a Mercedes Benz; two other cars; three boats and proceeds from the \$1 million sale of a farm where the Pintos bred Lusitano horses.

Pinto's 7,185-square-foot house presides over a wooded promontory on Lake Minnetonka. Valued at \$4 million in 2007, the house has a swimming pool and 50 yards of beach.

In addition to Transfeldt, Pinto is one of the six surgeons who receive payments from Medtronic. The others are Francis Denis, Timothy Garvey, Joseph Perra and James Schwender.

Schwender, 44, earned \$1.2 million from the practice and \$440,000 from royalties and consulting in

2008, divorce filings show. Schwender bought his lakefront home outside Minneapolis for \$2.6 million in 2005, according to real estate records.

'90 Percent Success'

Twin Cities Spine performed 1,100 lumbar, or lower-back, fusion surgeries in 2009, Dykes said. Of those, he added, 380 patients had degenerative disc disease and another problem such as stenosis, and 282 had degenerative disc disease alone.

Twin Cities Spine doesn't have any scientifically validated studies on the success of fusion for those in the latter group, Dykes said. He called them "the controversial patients."

Spinal fusion on back-pain patients is performed as a last resort after less invasive treatments fail, he said. Measuring outcomes has been difficult because researchers, doctors and payers can't agree on criteria for success, he said.

"Living Well With Back Pain," a 2006 consumer guide produced by Twin Cities Spine and published by HarperCollins, states that, "With proper patient selection and optimal surgical techniques, the success rate for spinal fusion surgery for back pain is now about 90 percent."

Two-Level Surgery

A letter from Pinto to patient Robin Washburn in 2005 said surgery offered "a very good chance" of success, adding that a "good to excellent outcome" would mean at least a 70 percent reduction in pain.

Two spinal fusion surgeries later, her back is worse than ever, said Washburn, who is 40 and a 911 dispatcher in Grand Rapids, Minnesota. Washburn's insurer, Blue Cross Blue Shield of Minnesota, paid \$80,000 for the two procedures.

"Before it was annoying. Now, it's pain every day, all day, worse when it's cold," she said in an interview.

Ninety-eight percent of Twin Cities Spine's post-operative patients who responded to a 2009 survey would choose or recommend the group for surgical care, according to Arrington's e-mailed statement. She said about a third of patients responded to the survey.

Patients that the practice recommended to Bloomberg News for interviews reported being happy with their surgeries. One of them, Jody Rasmusson, 48, of Minneapolis, underwent her second spinal surgery in three years by Dykes in October 2009. One year after the two-level fusion and decompression, the shooting pain in her back and legs was gone, said Rasmusson, a bank customer-service agent. A level is the space between two vertebrae; a two-level surgery means three vertebrae were fused.

Playing Football

Before Robert Gumatz, 60, had a five-level spinal fusion by Dykes in November 2009, the grain-company manager had so much back and hip pain he was losing the use of his legs, he said. He had stopped playing soccer with his kids and taking nightly walks with his wife. A year later, "I can play tackle football if I want to," said Gumatz, of Oakdale, Minnesota. "I know I'm an exception. I have no pain."

For 50 years, surgery was a calling at Twin Cities Spine. Led by surgeon John H. Moe, a pioneer in correcting scoliosis, or abnormally curved spines, the group's doctors rebuilt the twisted backs of children with polio and other malformations -- vertebra by vertebra.

They traveled at least 90 days a year, often paying their own way, to show doctors around the world how to mend childhood spinal deformities, said David Bradford, who spent 20 years at the practice before becoming chair of orthopedics at the University of California at San Francisco in 1991.

Adapting Fusion

At home, Bradford said surgeons operated weekly at Gillette Children's Hospital in St. Paul, Minnesota, usually for free. "It was just what you did; that's why we became doctors," said Bradford, now a professor and chair emeritus at UCSF's spine center. "We weren't in medicine to make gazillions."

While senior surgeons continue to research and treat crippling disease, Pinto and other protégés have also adapted the fusion techniques Moe pioneered to surgery for common back pain, said Robert Winter, the firm's research director.

Twin Cities Spine surgeons published articles on fusion techniques for back pain and presented results at professional meetings. Its financial relationship with [Medtronic](#), the largest maker of spinal implants in the U.S., began as early as 2002, when, according to a deposition by Pinto, he began receiving money from the company, which is based in Fridley, Minnesota.

Medtronic Money

In addition to the \$1.75 million it paid the six Twin Cities Spine surgeons this year, Medtronic and three other device companies give the practice a total of \$100,000 to \$500,000 for a fellowship program, Arrington said. Twin Cities Spine calls it the largest such program in the country and says it has trained 140 spine surgeons.

Medtronic also has [disclosed](#) contributing \$150,000 in 2008 to a non-profit that Schwender heads to spread the use of minimally invasive surgical devices. The contribution represented 95 percent of the non-profit's expenses that year, according to the organization's latest-available tax filings.

In 2004, Pinto was seeing Jean Kingsley, 57, a patient who had had two previous fusion surgeries and

was still suffering back pain. Pinto told her, according to a hospital report he wrote, that more “surgical treatment could provide her with some relief of her pain” if her symptoms “were extremely severe, unrelenting” and had “failed extensive conservative care,” which “appeared to be the case.”

Not Negligent

Her third operation, a daylong procedure by Pinto in September of that year, fused 13 vertebrae along her entire spine and was a disaster. Kingsley, of Milaca, Minnesota, returned home paralyzed from the waist down, according to hospital records in a lawsuit she brought against Pinto. A jury in Minnesota state court found earlier this year that Pinto was not negligent in the case.

The judge awarded \$46,616 in attorney’s fees to Pinto, which Kingsley said she can’t pay. She has appealed the decision. Her case is a “unique set of events for which even in retrospect there is no obvious explanation that one can prove,” Pinto said in his 2008 deposition, in which he estimated he performed 400 to 500 back surgeries a year.

Abbott and Twin Cities Spine billed a combined \$239,000 for the surgery, Kingsley’s records show. Insurer Medica says it paid about a third of that amount after a discount.

Kingsley arrived home in a wheelchair, wore a diaper for two and a half years and had a home health aide visiting to bathe her in bed, she said in a deposition in the case. As her condition improved, she said she was able to move short distances with the aid of leg braces and a walker.

‘I’m Paralyzed’

Today, Kingsley lives alone after the 2008 death of her husband. She said she takes medication for depression and doesn’t do “much of anything,” usually watching television and reading, and lives off Social Security benefits from her husband’s death. “Now I don’t feel any pain,” Kingsley said in an interview. “I’m paralyzed.”

Pinto co-authored a study in Spine in 2009 on 125 of his patients who had, like Kingsley, undergone fusions of four or more vertebrae. The study, which a Twin Cities Spine fellow presented at six surgical conferences around the globe, concluded that patients with extensive degenerative pain “can be successfully treated with surgical intervention.”

The Pinto study showed why back-pain patients should avoid spinal fusions, said Stanford University’s Carragee. The paper tracked progress in only 80 of the 125 surgical patients; “what happened to the other 45 patients?” Carragee asked.

Lifting a Keg

Twenty-seven of the 80 patients needed a second surgery, while about 40 percent of the patients had complications, including 5 percent of the men who suffered permanently diminished sexual function,

Carragee said.

“This should make you pretty cautious about doing this kind of stuff,” he said.

Twin Cities Spine, in its statement, said Pinto’s study was the first to report on such extensive fusion surgery for degenerative back pain, an operation it said “is in no way comparable” to less complicated procedures.

Schwender first performed fusion surgery on Catherine Engels in May 2001, after finding she had a herniated disc. She came to see him again on June 4, 2003, complaining of sharp back pain, her medical records show.

Engels, now 50, received Schwender’s support for a workers’ compensation claim, in which she said she injured her back lifting a keg at a liquor store where she worked in July 2000. Schwender said in a deposition that the incident was “a significant contributing factor” to Engels’s back problems.

‘Constant, Sharp Pain’

The workers’ compensation judge [rejected](#) her claim, finding “multiple significant inconsistencies” between her and Schwender’s testimony, on one side, and the medical records submitted by six doctors Engels saw before Schwender, on the other. Two of those doctors said Engels hadn’t attributed her back pain to any specific injury, and others said Engels attributed the pain to lifting patio brick, the judge found.

Schwender operated a second time on Engels in January 2004, removing the screws and rods he’d put in her spine and decompressing the spinal canal. It didn’t help. By then, Schwender told Engels, the rods and screws had shifted and caused permanent nerve damage, she said in an interview. Now she has “constant, sharp pain” down her left leg, treated with drugs and a neurostimulator in her back designed to send out current that interferes with pain signals.

“I went through with fusion thinking it would be the cure- all,” Engels said. “It wasn’t.”

OxyContin, Hydrocodone, Elavil

Dan Bebault was suffering from lower back and leg pain when he visited Twin Cities Spine’s Garvey in May 2006. Garvey discussed surgery with him and told him he’d “likely” be able to return to light work three to six months afterwards, according to Bebault and notes Garvey made on the case. “He pretty much talked me into it,” Bebault said.

The fusion took place in August that year. When Bebault returned to see Garvey five months later, he said, his life was falling apart. The pain had spread to his neck and arms, and OxyContin, hydrocodone and Elavil weren’t helping much. Bebault’s wife had left him after the surgery; he hadn’t worked in four years.

Garvey wasn't sympathetic, said Bebault, a 53-year-old former machinist who lives in Brooklyn Park, Minnesota. "He said my life was like an old country-western song and he didn't want to hear about it," Bebault said in an interview at his home. "He said come back if I want more surgery."

Methadone Overdose

Additional fusion surgery for Bebault's neck "would be an option," Garvey's chart notes from this time say. Bebault, now reunited with his wife and on Social Security disability, decided against more surgery and quells the pain in his back and neck with 120 milligrams a day of morphine, plus occasional vicodin, valium and amitriptyline, an anti-depressant.

He said he feels "withdrawals" when his morphine wears off, shaking and sweating. His surgery cost his former employer's [workers' compensation](#) insurer \$48,633; Garvey's fee was \$5,870.

"The patient is like a piece of meat; everybody's making money off the guy," Bebault said.

Garvey did a three-level spinal fusion on Ross Tamminen in April 2006. Six months later, Tamminen, a heavy-equipment operator, reported severe pain again in his back and legs, according to documents from a [case](#) in state workers' comp court.

As a treatment option, Garvey proposed more surgery to examine the fusion site, remove the implants in Tamminen's spine, and perform decompression. His employer's insurer denied a coverage request, saying surgery wasn't warranted, according to court filings.

The rest of the story comes from Tamminen's mother, Barbara Grove. Denied federal disability benefits and in intractable pain, Tamminen ran out of money for painkillers, she said, and began taking methadone obtained through friends.

He died of an overdose on June 20, 2008, 26 months after spinal fusion. He was 41.

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