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## Law clashes with medicine over cause of joint destruction

### Study challenges lawsuits accusing pain pumps of damaging joints

By [Robert McCoppin](#), Chicago Tribune reporter

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Exercising on her lunch break, Angela Mitsias felt a twinge in her shoulder. She didn't think much of it and went back to work.

By the end of the day, she couldn't move her arm without pain. She never imagined treatment would make it worse or that she would still have debilitating pain years later.

After surgery to repair torn shoulder cartilage called labrum tissue, Mitsias developed a mysterious condition in which the cartilage disintegrated. Eventually, the problem got so bad she was forced to have a partial joint replacement in 2006.

"I was a wreck," the Schaumburg woman said. "It just took over my life."

Mitsias was the victim of a rare, devastating and painful condition called chondrolysis — the destruction of joint cartilage — which leaves bone grinding against bone. There has been a wave of such cases in the last decade, often after surgery and usually affecting young, otherwise healthy people.

The injuries have led to lawsuits by Mitsias and hundreds of others alleging the condition is caused by misuse of a pain pump often used to infuse anesthesia into the joint after surgery.

Dr. Anthony Romeo, who operated on Mitsias to fix the previous damage and relieve her pain, calls her condition part of "a growing orthopedic catastrophe." He is one of two leading local doctors who took part in a new study that says, in effect, "not so fast," that other factors might also cause chondrolysis.

The study highlights the gap between law and medicine over how to determine the cause of a relatively new condition. As a result, the researchers and their work are being drawn into ongoing litigation.

Mitsias' original surgery a decade ago, when the former gymnast was 30, included the use of suture anchors, a hot probe and a pain pump — three of the main factors that have since been associated with the development of chondrolysis.

"She's one of the first patients where it all came together," said Romeo, a physician for the [Chicago White Sox](#). "I knew we were into something unusual."

Total cartilage destruction in shoulders was almost unheard of until the last decade, when doctors began using



Angela Mitsias' shoulder is treated Thursday by a physical therapist at Athletico in Chicago. Mitsias has chondrolysis, a joint malady whose cause is in dispute. (José M. Osorio, Chicago Tribune / November 10, 2011)

pain pumps in arthroscopic surgery. Although such pumps are used routinely in other parts of the body, the U.S. Food and Drug Administration denied manufacturers' requests to approve the pumps for use inside a joint — yet manufacturers marketed the devices for such infusions, plaintiffs' attorneys said.

Since 2005, a series of studies has associated pain pumps with the spike in chondrolysis cases. This year, a University of Washington study of 375 arthroscopic shoulder surgeries found that 49 of the patients developed chondrolysis and all of them had been treated with pain pumps. Of those who did not receive pain-pump infusions, none developed the condition.

In one case study, a patient who had surgery on both shoulders developed chondrolysis only in the shoulder that had been treated with a pain pump. Separate studies also found that the anesthesia used in pain pumps can be toxic to the cells that make up cartilage.

As a result, in 2009 the FDA stated that pain pumps might contribute to chondrolysis, warned doctors not to use them inside joints and required manufacturers to alert doctors and patients.

The controversy attracted the attention of Romeo, director of the shoulder and elbow section at Rush University Medical Center, and another nationally known local doctor, Brian Cole, head of the Cartilage Restoration Center at Rush and team physician for the [Chicago Bulls](#).

They did not use pain pumps but treated numerous patients who had developed chondrolysis under other doctors' care. To get a better idea of what was causing the problem, they took part in a comprehensive review of all the medical literature on the subject.

By looking at 830 cases of chondrolysis in all joints dating to 1930, the study found that numerous factors could play a role in chondrolysis. Many early cases occurred in the hips, due to conditions such as birth defects or infections.

Pain pumps were a frequent factor in those who developed chondrolysis in the shoulder, but the study also pointed to other factors, including protruding metallic suture anchors placed in the joint during surgery, radio-frequency heat treatment, surgical trauma and dyes. To prevent misdiagnosis, the authors tried to set parameters to better define chondrolysis, suggesting some cases are actually common osteoarthritis.

The findings have prompted a public dispute among leading researchers in *The Journal of Bone and Joint Surgery*, where their papers were published.

One researcher who is critical of the new study's findings, Dr. Benjamin Busfield, an orthopedic surgeon in Antioch, Calif., said the new research arbitrarily tries to limit criteria for defining the condition. He is a consultant for plaintiffs in chondrolysis litigation.

Another critic, Dr. Frederick Matsen III, a professor of orthopedic surgery at the University of Washington, was a co-author of the 2005 study that found a strong correlation between pain pumps and shoulder chondrolysis.

He called it "curious" that besides Romeo and Cole, the other four authors of the new study are affiliated with Advance Health Solutions, a consulting and research firm whose clients include pharmaceutical and medical device companies.

Advance Health President and CEO Maryam Navaie, one of the authors of the new study, in turn is critical of the 2005 study, which she said has "a poor threshold of validity." She noted that many of the cases involving pain pumps did not result in chondrolysis.

Navaie accused Matsen of being "in cahoots" with plaintiffs in chondrolysis lawsuits, noting that a federal judge

in Oregon ruled last year that Matsen's testimony was tainted by litigation bias and was "unreliable and inadmissible."

Navaie emphasized that Advance Health has not been hired by anyone to work on chondrolysis or pain pumps, and none of the doctors has received any compensation for their research. She said the firm does research on a wide variety of conditions and wanted to investigate the cause of a disease that had become more common. She declined to say whether the company had done other work for pain pump manufacturers or other defendants, citing her clients' privacy.

Navaie said that as a result of her research, her firm was subpoenaed multiple times in an attempt to discredit the study because of funding sources, which she said has a "chilling effect" on research. Her team's work has also been cited in a multiple court rulings in pain pump cases.

Beyond the squabble among doctors, the dispute highlights the gap between legal and medical standards of proof. Civil courts require a preponderance of evidence to prove a case, meaning that something is more likely than not.

On that basis, the judge in one case found that the overall evidence "sufficiently, if not conclusively," supports the theory that pain pumps caused chondrolysis. Some cases have been settled, some are pending and others have been dismissed by judges for failing to show evidence the pump manufacturers were at fault.

Some doctors have been sued, but most of the suits have gone after the pump manufacturers or distributors, on the theory they failed to test their products adequately and warn doctors against using them inside joints. One of the biggest manufacturers, Stryker Corp., in Kalamazoo, Mich., and distributor DJO Global Inc., in Vista, Calif., declined to comment.

But I-Flow Corp., in Lake Forest, Calif., issued a statement that it stands by the "safety and efficacy" of its ON-Q Painbuster pump, which the company said has been used by more than 2 million patients for various surgical procedures and relieves pain while greatly reducing the need for narcotics. Although "there is no definitive established causal relationship," I-Flow stated, it was first in the industry to warn against using the pumps inside joints.

Though the court fights continue, most doctors have stopped using pain pumps inside joints. Despite the new research, Tom Powers, an attorney for pain pump patients, said, "In the medical community, there's an overwhelming consensus among doctors that it's dangerous. They don't do it because there's a powerful association between pain pumps and chondrolysis."

But correlation does not prove causation. Ultimately, medical research will require proof more like a criminal case — beyond a reasonable doubt.

So while Romeo and Cole concede that pain pumps might play a role in chondrolysis, they say that court rulings shouldn't determine treatments — further research should.

Although chondrolysis has no cure, because cartilage does not regrow, Cole said, better knowledge about its causes and diagnosis could lead to better prevention and care.

One of his patients, Matt Wenninger, was a college wrestler who repeatedly dislocated his shoulder, to the point it popped out of place when he rolled over in bed. After surgery to fix it, he developed so much pain, even with narcotics, that he could hardly move his arm. Though he hadn't had a pain pump, he did have two protruding suture anchors inside his shoulder that his doctor told him had ground down his cartilage.

Cole transplanted cartilage from a deceased donor into Wenninger's shoulder. Now 27 and living near

Minneapolis, Wenninger coaches wrestling and is able to throw a football and work on his house. Cole says patients like Wenninger motivate him to get to the bottom of the matter.

"I couldn't care less about the legal issues," Cole said. "We're just here to figure out the best decisions for my patients. Who's best for transplantation and joint replacement? How can we prevent this from happening?"

Mitsias, the former gymnast who has since become a singer-songwriter, is still trying to recover.

"The future is scary," she said. "I'm probably facing some form of therapy the rest of my life."

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