



# Knee Surgery No Better Than Placebo

## Sham Surgery for Arthritic Knees as Effective as the Real Thing

By Melinda T. Willis

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On a scale of zero to 10, Eutimo Perez Jr. says the pain in his knee that was once "worse than 10" is no more.

Perez, who suffers from the degenerative joint disease osteoarthritis, took part in a clinical trial designed to test the efficacy of arthroscopic surgery on osteoarthritic knees, and has been pain-free for more than two years since.

The interesting thing, though, is that Perez was in the "sham surgery" group of the study and the researchers did almost nothing to him.

Osteoarthritis, which afflicts more than 20 million Americans, is characterized by the breakdown of cartilage in the joints. Oral medications as well as lifestyle changes can treat the disease, but for some patients, arthroscopic surgery ??? in which damaged cartilage is scraped or flushed out with the aid of a thin viewing scope ??? is also an option.

Perez was assigned to the placebo group of the trial: He was given anesthesia and doctors made incisions in his knee so that it looked as though he had an arthroscope inserted. This sham surgery group was compared to other patients who underwent an actual arthroscopic procedure.

The study, published this week in the New England Journal of Medicine, found some surprising results.

"The groups were all reporting improvement; it's just there was no greater benefit in any of the groups compared to the placebo," Dr. Bruce Moseley, lead author of the study and clinical associate professor of orthopedic surgery at Baylor College of Medicine in Houston, told ABCNEWS' Jackie Judd.

This experience has left Perez with a strong understanding of the placebo effect and of how belief that a surgery can relieve pain may actually do just that. "It's a mental thing," he said. "I think that if you believe in something, you can get well."

And for the medical community, it has led to the understanding that arthroscopic surgery, as performed an estimated 200,000 times a year for the treatment of osteoarthritic knees, may be useless. "My opinion is we probably shouldn't be doing it," said Moseley.

### Suspicious Confirmed

For some physicians who share Moseley's opinion, this new study confirms their suspicions.

"It's my impression that arthroscopy in the osteoarthritic patient has already become less popular primarily because it hasn't had the benefits that people thought it would," said Dr. William W. Tipton Jr., executive vice president and CEO of the American Academy of Orthopedic Surgeons in Rosemont, Ill.

It was believed that the often considerable pain associated with the condition could be improved surgically through flushing out and removing cartilage debris in the knee joint.

"Practically every report, every study that was ever done said that the majority of patients were improved after they had the surgery," said Moseley. "It's just that nobody ever said they were well. It was clear that many of these patient's early improvement would digress over time and they would end up with [knee] replacement surgery."

### The Power of Placebo

Up until now, no one had tested this surgical procedure against a placebo or "sham surgery" to ferret out how much of the improvement seen following surgery is due to what the surgery actually does or to the placebo effect.

"Any treatment for pain has an enormous placebo effect," said Dr. Gary Firestein, chairman of the Food and Drug Administration's Arthritis Advisory Committee and chief of rheumatology, allergy and immunology at the University of California at San Diego School of Medicine. "The response rates are generally in the 20 to 40 percent range for almost all studies, and higher percentages are associated with more aggressive and invasive approaches where the belief system is firmly entrenched."

That highlights the importance of conducting placebo-controlled trials for surgical procedures, but that undertaking involves considerable ethical issues due to the invasive nature of surgery. For example, questions about the ethics of sham surgery were raised following a study on surgical implantation of fetal cells to treat Parkinson's disease. All subjects had holes bored into their skulls, but only half were given any treatment with the cells.

The more benign nature of arthroscopy has lent itself to less criticism. Many experts agree that the design of the current study was fair by ethical standards and that in this case it was important to determine whether such a common procedure was indeed effective.

"More important is whether it was ethical to perform tens of thousands of these invasive procedures on patients without any documentation that it alters the natural history of disease, quality of life or functional outcome," said Firestein.

### Effect on Practice and Policy

Because this is the first such placebo-controlled study on arthroscopy for osteoarthritis, it is too soon to say whether the findings of the study will have any major impact on insurance coverage or physician practice.

Aetna, one of the nation's largest health-insurance providers, currently covers the procedure and says it plans to have its medical directors review the information before it considers making any changes in coverage.

Other experts would like to see the results duplicated before instituting widespread changes. "I think this is an interesting study ??? I'd like to have a couple of other centers repeat [it]," said Tipton.

One issue that remains is whether these findings would hold true for women, as the current study was conducted only in men. "Since osteoarthritis of the knee is more prevalent in women than in men, it is not clear that patients in the community always fit the study criteria precisely," said Firestein.

As for Perez, no matter what future research may find, he is happy with how everything has worked out. "I can dance, I can go away fishing, I can play basketball and it doesn't bother me one bit. Everything is wonderful."

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