Thousands got Exactech knee or hip replacements. Then, patients say, the parts began to fail

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Ron Irby expected the artificial knee implanted in his right leg in

September 2018 would last two decades—perhaps longer.

Yet in just three years, the Optetrak implant manufactured by Exactech in Gainesville, Florida, had worn out and had to be replaced—a painful and debilitating operation.

"The surgery was a huge debt of pain paid over months," said Irby, 71, a Gainesville resident and retired medical technologist with the Department of Veterans Affairs.

Irby is one of more than 1,100 patients suing Exactech after it began recalling artificial knees, hips, and ankles, starting in August 2021. A letter Exactech sent to surgeons blamed a packaging defect dating back as far as 2004 for possibly causing the plastic in a knee component to wear out prematurely in about 140,000 implants. Many patients argue in hundreds of lawsuits that they have suffered through, or could soon face, challenging and risky operations to replace defective implants that failed.

Although Exactech does not offer an express warranty on its products, the company stresses the durability of its implants in advertising, even suggesting they likely will outlive their human recipients.

Exactech, which grew over three decades from a mom-and-pop device manufacturer into a global entity that sold for $737 million in 2018, declined comment, citing the "ongoing litigation," said company spokesperson Tom Johnson. In court filings, Exactech has argued that its products are not defective and have "an excellent history."

A KFF Health News review of thousands of pages of court filings in patient lawsuits, a pending whistleblower lawsuit, and other government records shows that the company is being accused of downplaying or concealing evidence of product failures from patients and federal

regulators for years. In hundreds of instances, according to government records, the company took years to report adverse events to a federal database that tracks device failures.

In his suit, Irby alleges that Exactech "knew or should have known" that the Optetrak "had an unacceptable failure and complication rate." He said Exactech used packaging materials of "an inferior grade or quality."

"I think they were cutting corners to improve their bottom line," Irby told KFF Health News.

Exactech denied the allegations in a legal filing in Irby's suit, in which it described the Optetrak device as "safe and effective."

A family affair

Surgeon William "Bill" Petty chaired the orthopedics department at the University of Florida in Gainesville, when he, his wife, Betty, and Gary Miller, a biomedical engineer and fellow faculty member, formed Exactech in November 1985. The Pettys served in corporate roles until retiring in early 2020. Their first hire was their son David in 1988, who remains on Exactech's board of directors.

Exactech's fortunes started to take off in 1994, when it inked a major deal to license and market the Optetrak knee implant based on designs by surgeons and engineers at the prestigious Hospital for Special Surgery in New York City. That alliance won Exactech instant credibility in the fiercely competitive device industry.

So did its pedigree as a "surgeon-focused" business with a family-run vibe, small enough that surgeons considering its wares could meet the owners and tour its Florida plant.

Building on that goodwill, Exactech's sales shot past $124 million in 2007, about half generated by the Optetrak knee system.

"It's not just a road we're on, it's a trail we're blazing," the company boasted in sales literature aimed at surgeons.

Exactech's corporate confidence belies years of warnings and doubts about the durability of the Optetrak, according to whistleblowers—one whistleblower called it an "open secret" inside the company. Notably, there were concerns about the fragility of a finned tibial tray, one of the four pieces of the knee replacement that fits into the shin bone, according to the whistleblower lawsuit.

For starters, several surgeons complained that the knee implants loosened prematurely, causing patients pain and limiting their ability to move around, court records allege.

While 95% of artificial knees should last at least a decade, surgeons had to pull out and replace many Optetrak components—a complex operation known as revision surgery—much sooner, according to allegations in patient lawsuits.

Christopher Hutchins, a Connecticut orthopedic surgeon who relied on the Optetrak finned devices for more than 350 knee surgeries, said in a court deposition that some loosened in as little as two to three years. He called that "awfully premature" and "extraordinary."

Hutchins vented his frustrations in a brief meeting with Exactech co-founder Bill Petty at a Rhode Island hospital in either 2006 or 2007, according to his deposition. Petty told him at the meeting he "realized that it was a problem" with the device, according to Hutchins.

"I was somewhat struck that if they knew there was a problem why it

wasn't being addressed and why the product wasn't being pulled from the market," Hutchins testified in the November 2021 deposition.

"There was no disclosure or transparency."

Older patients not only suffered physical pain, but also felt an "emotional burden" from facing revision surgery in which results often are "not as good as the first go around," Hutchins explained during his deposition testimony."I'm in the business to try to make people better, and when things fail, I take it to heart."

Hutchins was not the only surgeon alarmed by what he says were early failures of the Optetrak devices and the company's tepid response.

'Popping out'

In August 2005, Maine orthopedic surgeon Wayne Moody told company officials that Optetrak had loosened and needed to be revised in 25 out of 385 operations he had performed over the previous four years, according to meeting minutes filed in court.

One knee implant gave out in just nine months, Moody told the group, according to the minutes.

In a deposition, Robert Farley, a former Exactech sales agent who filed a whistleblower lawsuit in 2018 alleging fraud by the company, alleged that he heard two colleagues joke about Moody's tribulations at a national sales conference.

Moody "probably had 50-something revisions. … They're just popping out right and left," the sales agent said, according to Farley's suit.

Fellow whistleblower Manuel Fuentes, a former Exactech senior product

manager, testified in a deposition that pulling the product off the market around 2008 "would have been the ethical and moral thing to do."

At a meeting in early 2008 attended by the company's top brass, including Bill Petty, the company's marketing director at the time, Charley Rye, floated the idea of a recall, Fuentes said. Company executives shot that down as "financially detrimental," Fuentes testified in a sworn declaration filed with the court.

Asked about the meeting during a December 2021 deposition, Petty replied, "I don't recall that anyone suggested a recall."

'Silent recall'

Exactech discussed the loosening problem in an internal memo that said between 2006 and 2009 the company "began to get some negative feedback" about the Optetrak "that was at times confounding and difficult to process," court records show.

The discouraging reports ranged from complaints of early revisions from at least 10 U.S. surgeons and surgery practices in several of the more than 30 countries where Exactech sold the implant, court records show.

The results did little to dim Exactech's prospects. From 1994 through April 2022, Exactech sold 58,763 Optetrak devices with finned trays for use by 514 surgeons nationwide, according to an affidavit by a company official.

Many lawsuits argue that instead of warning patients and surgeons about the loosening problem, Exactech replaced the finned tray component in its newest products, a strategy device industry critics refer to as a "silent recall." Exactech denies that and said in a court filing that design changes it made were part of a "natural evolution" of the Optetrak.

Even as Exactech rolled out newer generations of the Optetrak, the company faced lawsuits and other criticism alleging it had failed to come clean about unusually high surgical revision rates.

Late notices

The Food and Drug Administration runs a massive, public, searchable databank called MAUDE to warn the public of dangers linked to medical devices and drugs.

Manufacturers must advise the FDA when they learn their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that might recur and cause harm. Those reports must be submitted within 30 days unless a special exemption is granted.

But court and government records show that reports of adverse reactions tied to Exactech's implant sometimes took years to show up in the government database—if they were reported at all.

Exactech failed to advise the FDA of dozens of Optetrak early revision complaints lodged by orthopedic surgeons Moody and Hutchins, a company representative acknowledged in a court filing.

KFF Health News downloaded the FDA data and found about 400 examples in which Exactech reported adverse events to the MAUDE database two years or more after learning of them.

FDA inspectors who combed through Exactech's internal files in 2017 cited the company for failing to undertake an "adequate investigation" of complaints, according to FDA records cited in court filings.

In court filings, Exactech steadfastly denied Optetrak has any defects. Instead, it blamed the loosening problem on surgeons, saying they had

failed to cement the knee implants into place correctly or misaligned them.

The company said it had no obligation to report poor outcomes tied to mistakes by surgeons—even though the FDA requires companies to report injuries involving "user error." In 2022, a federal judge in the whistleblower case, in denying a motion to dismiss, found that Exactech was "hard-pressed" to claim it was not obligated to report the adverse events.

The three whistleblowers are accusing Exactech of fraud for allegedly selling defective products to Medicare and other federal health care programs. The case is pending in federal court in Alabama and Exactech has denied any wrongdoing. Exactech in mid-August filed a motion to dismiss the case.

Lawyers for more than 300 injured patients suing in Alachua County Circuit Court in Florida are pressing for full disclosure of 2,435 complaints to the company alleging deficiencies with Exactech knee products, which the company admits receiving as of the end of April.

In other pending lawsuits, patients argue the company pointedly ignored evidence of chronic safety issues to fuel profits.

Keith Nuzzo, of Litchfield, Maine, is one. He alleged that Exactech "cut corners, utilized inferior manufacturing practices … [and] only disclosed information or took corrective action if contacted by regulatory authorities."

Nuzzo had a right knee replacement done by orthopedic surgeon Moody in February 2012 and a left knee implanted a week afterward.

His right knee became painful and wobbly about four years later and a

second surgeon replaced it in August 2016. The left knee gave out in November 2020, also requiring replacement, according to the suit.

Despite the revisions, Nuzzo lives with "daily knee pain and discomfort," which limits his "activities of daily living and recreation," according to the suit. The case is pending. As of mid-September, Exactech had not filed an answer.

No guarantees

In advertising directed at surgeons, Exactech boasts about the long life of its implants.

One sales brochure states that the Optetrak "demonstrated 91-99 percent implant survival rates" over just under a decade. That is consistent with, if not superior to, industry standards, though as a rule of thumb many surgeons expect implants to last 15 to 20 years, sometimes longer.

The mounting legal claims allege many Exactech knee and hip implants have worn out well before their time.

The KFF Health News analysis of more than 300 pending cases in Alachua County found that surgeons removed about 200 implants after less than seven years. Some people in the sample, whose surgeries spanned more than two dozen states, were awaiting revision procedures. In the federal court sample, patients alleged that half of the 400 implants that were removed lasted less than six years.

Advertising materials aside, Exactech is circumspect in describing the reliability of its implants when it speaks to courts. In a 2021 filing, the company noted that the Optetrak comes with no express warranty.

How long it lasts "depends on a multitude of factors, including those

pertaining to surgical technique and the particular patient," the company said.

Promoting the products

Exactech's focus on its surgeon customers includes paying handsome consulting fees to some orthopedists who have used the company's implants in the operating room or promoted them in advertising.

Exactech paid surgeon consultants $23.2 million combined from the start of 2013 through the end of 2022, the most recent year available, according to a government database called Open Payments.

In promoting the Optetrak in sales materials, Exactech touted "excellent results" achieved by orthopedic surgeon Raymond Robinson. Left unsaid: Exactech paid Robinson more than $900,000 in consulting fees and other payments from 2013 through 2022. In a court filing, Exactech denied any consultants "were compensated in exchange for product promotion." Robinson could not be reached for comment.

Exactech's sales brochures also boast that surgeons "around the world have documented excellent results with the Optetrak knee system."

Yet Exactech bottled up a succession of sharply negative reports from other countries, while working to discredit others, according to internal company records filed in court by the whistleblowers.

One surgery group in France concluded in 2012 that nine of 110 Optetrak procedures required revision due to loosening in under three years, for instance. Exactech disputed the findings in a published response, and in a court filing said the conclusions were "based on incorrect information and a flawed understanding of the true causes."

A hospital in Buenos Aires, Argentina, reported that 25% to 30% of Optetrak knees required revisions in under two years, according to whistleblower Fuentes.

The Australian implant registry criticized Optetrak's reliability as early as 2007 and in several later years. In response, Exactech executives said in depositions and court filings that they traced many of the poor results to a single hospital and three surgeons who failed to align the implants correctly.

The Australian registry pegged Exactech's revision rate at 19.4% at seven years and 22% at 10 years, the worst of any knee implant on the market, which led the government health system to stop purchasing it, court records allege. Exactech denied the allegations in a court filing.

James Brooks, a retired Texas orthopedic surgeon, said in a court affidavit that he believed Exactech had an obligation to tell surgeons about the poor outcomes overseas rather than touting rosy results tied to doctors on its payroll.

In the 2021 affidavit, Brooks recalled implanting the Optetrak knee in a Dallas man in 2011, only to confirm from X-rays that it was failing in 2017 and needed to be replaced two years later. Brooks said he would have steered clear of Optetrak had he known of its "much higher failure rate than comparable products."

Clicking sounds

Laura Grandis is suing Ohio orthopedic surgeon and Exactech consultant Ian Gradisar, who received $132,720 from the company, including research payments, from 2013 through 2022, according to government records.

Gradisar's father, Ivan, also an orthopedic surgeon, served on the original Optetrak design team. In 2008, Ian Gradisar helped his father with an audit of "patient outcomes" commissioned by Exactech. The audit showed that 12 of 47 Optetrak patients operated on over the course of 15 months required revisions, giving the son "first-hand knowledge of the failing and defective Optetrak," Grandis alleges in her suit.

Ian Gradisar put an Exactech implant in Grandis' left knee in Akron, Ohio, in November 2020.

In early 2021, she had "severe" pain in her knee and needed a cane or a walker to get around, according to the suit.

Gradisar told her the knee had failed, which he said was "very rare and only happened 5% of the time," according to the suit.

Grandis had revision surgery in July 2021 with an Optetrak implant. Some seven months later, she felt pain that worsened throughout the day. She tried ice and rest, but that did not work. Her knee hurt when she put weight on it and started making a clicking sound when she moved, according to the suit.

In June 2022, Grandis received a "Dear Patient" form letter from the hospital where her surgery was performed notifying her of the Exactech recall.

Gradisar's office told her the surgeon could not see her until October 2022 "as he was inundated with phone calls from patients about the Exactech recall," according to the suit.

In response to the suit, Exactech denied the allegations, including that its knee implants had "increased failure rates." The case is pending. Gradisar and his lawyer did not respond to requests for comment.

But in a court filing, Gradisar denied any defects in the implant and said he "provided quality care and treatment" to Grandis.

In December 2022, Grandis ended up having a second revision operation that kept her hobbling around on crutches for six weeks, according to her suit.

Total recall

Two years after the initial recall, Exactech and its owners—past and present—face a rush of lawsuits demanding accountability for alleged patient injuries.

Most of the suits in the Alachua County group name Bill, Betty, and David Petty and Miller as defendants for their roles at Exactech. Their attorney did not respond to requests for comment, but in May, the defendants jointly filed a motion to dismiss, arguing that the suits fail "to allege sufficient facts to impose liability."

Many suits in the federal court cluster also name as a defendant TPG Capital, a Texas-based private equity firm that paid $737 million to acquire Exactech in February 2018. TPG declined to comment but has filed a motion to dismiss the cases.

In one recall letter sent to surgeons, Exactech acknowledged that the data from the Australian registry confirmed that Optetrak had "statistically significant" higher rates of revisions than knee implants made by other companies—a conclusion it had previously disputed.

The letter adds that Exactech is "uncertain" if the packaging defect is the "root cause" of Optetrak's poor performance. An FDA "safety communication" issued in March said the agency is working with Exactech to assess whether other implants packaged in the defective

bags pose similar risks.

Exactech lawyers say the company may not be to blame for every implant that wears out unexpectedly.

In a November 2022 hearing, Exactech attorney Michael Kanute said wear of polyethylene implant components is a "known risk no matter who makes them." He said the patient's size and activity level as well as the technique of the surgeons could also be factors.

"So every case is different," he said.