Medical Mess

Implants in Jaw Joint Fail, Leaving Patients In Pain and Disfigured

Teflon-Coated Disk Seemed A Boon for TMJ at First But Had Little Testing

'Surgical Merry-Go-Round'

By Bruce Ingersoll and Rose Gutfeld
Staff Reporters of The Wall Street Journal

Roblyn Ruggles is weeping. "This isn't my face," she says. "I used to be real pretty."

Eight oral-surgery operations have left her disfigured, without jaw joints, her mouth permanently agape. She can't bite into a sandwich. She can't purse her lips for a kiss.

And alone at night, she can hardly bear the muscle spasms and the pain. "It never goes away; it's God-awful pain," says the onetime nurse, who lives in Cuyahoga Falls, Ohio. "I have to pretend it's something else to hold onto my sanity."

Ms. Ruggles, 37 years old, is a victim of biomaterials engineering gone awry, caught up in a medical catastrophe that is claiming new casualties almost every day. The cause of her pain and disfigurement: synthetic jaw implants aggressively marketed by Charles Homsy, founder of Vitek Inc., without adequate premarket testing. Hundreds of oral surgeons embraced the so-called interpositional implants as a breakthrough of sorts in the 1980s. One prominent surgeon, John Kent, lent his name to Vitek products and served as Dr. Homsy's clinical consultant.

An Unfolding Disaster

More than 25,000 patients afflicted with the same jaw disorder as Ms. Ruggles—temporo-mandibular joint syndrome, or TMJ – received Vitek implants before liability-insurance problems forced the small Houston company to take them off the market in mid-1988. In 1990 the Food and Drug Administration forced the company to issue a safety alert and eventually seized its products.

But for thousands of patients, the implant affair is far from over. Medical experts now expect a high percentage, if not all, of the implants to break up into microscopic fragments and beget a biochemical reaction in patients that erodes jaw bone, creating many other painful complications. Says Larry Wolford, a Dallas oral surgeon: "This is the worst disaster our specialty has ever faced."

It is one with many contributing factors. Federal regulation of the medical-devices industry was lax when the device was introduced in 1983. Vitek was headed by a zealous entrepreneur who, according to the FDA and experts in biomechanics, neglected to run a critical test of the implant's durability. The company was quick to discount adverse findings in animal experiments – all done after the implant was in widespread use – and was slow to accept the implications of early implant failures.

TMJ disorders can produce arthritis, jaw and facial pain, headaches, earaches, clicking sounds in the jaw, and restricted jaw movement. The temporomandibular joint is terribly complicated: It lets the lower jaw, or mandible, move up and down, side to side, forward and back, and in many combinations as a person speaks, bites, chews, swallows, smiles, laughs, grimaces. It is an exquisite network of nerves and muscles, and it isn't well understood. No one knows, for instance, why TMJ disorders afflict women more than men; 90% of the Vitek implant recipients are women.

Charles Homsy

Treatment of TMJ disorders has long occupied a medical gray area. Orthopedic surgeons have stayed away from it, fearful of slipping up in an area so close to the brain, ear and facial nerves. But oral and maxillofacial surgeons have been more aggressive in treating TMJ, and when the Vitek implant came on the market, many turned to it enthusiastically.

Compounding the tragedy, new research in the Netherlands suggests that the best treatment for TMJ may be none at all, because most TMJ disorders abate in a few years. Some experts in the U.S. also say there is no justification for surgical intervention in TMJ cases. "The worst post-surgical cases are far worse than the worst cases in their natural, pre-surgical states," says Joseph Marbach of Columbia University's school of public health.

Blaming Surgeons

Dr. Homsy, a chemical engineer who was president and majority owner of now-defunct Vitek, blames surgeons for putting his products in the wrong patients or for botching the procedure. The implants, he asserts, "weren't at fault; poor surgical judgment and technique were." If there were any gaps in testing, he says, it is the fault of Dr. Kent.

Dr. Kent, head of oral and maxillofacial surgery at Louisiana State University, blames Dr. Homsy for inadequate testing. "The ultimate responsibility for testing is the manufacturer's," says Dr. Kent. Counters his erstwhile friend, who contends that he urged Dr. Kent to conduct the appropriate tests: "I'm a scientist. I can't

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operate on animals."

Ms. Ruggles, for one, has been on a "surgical merry-go-round" ever since her implants came out in June 1989. Doctors have tried just about every option – a dermal tissue implant, a silicone rubber implant, a pair of Vitek total-joint implants – without any success. Her surgery bills to date total $280,000, only partly covered by her husband's medical insurance.

Thoughts of Suicide

In Tucson, Ariz., oral surgeon Stephen Harkins is treating 100 implant patients, 20 of whom he says are suicidal. "They are barely functional, under heavy pain medication and antidepressants," he says. "They have had significant damage to the bones and muscles of the face and nerve damage." Some have had to have their jaws rebuilt with ribs and cartilage from their own bodies or from cadavers, with mixed results. "These people aren't kooks," says Dr. Harkins. "They look like they've spent 10 years in Auschwitz."

Thousands of patients already have had their failed implants removed, and thousands more will have to have theirs "explanted" as well. While many aren't showing any overt symptoms of failure, X-rays and CT scans reveal the onset of bone loss. Deborah Zeitler, an associate professor of oral surgery at the University of Iowa, says more than 90% of her patients with implants already have had them out. Douglas Morgan, a surgeon in La Crescenta, Calif., reports finding an implant had eroded a hole into a patient's brain.

An Oval Disk

Other surgical implants have failed, of course, but few so completely. Silicone-gel breast implants are failing at a rate of about 1%. But it now looks as if the failure rate of the interpositional implant, or IPI, ultimately "could be 100%," says Daniel Laskin, editor in chief of the Journal of Oral and Maxillofacial Surgery.

The IPI, Vitek's main product, was widely used to replace an oval disk of cartilage that acts as shock absorber between the temporal and mandibular bones. The disk can easily be dislocated by a blow to the jaw or irreparably damaged by too much grinding or clenching of the teeth.

The IPI was nothing more than two layers of plastic laminated together – a super-thin sheath of Teflon FEP, which is a smooth DuPont Co. polymer, and a wafer of highly porous Proplast, which is a biomaterial concocted by Dr. Homsy out of another DuPont polymer, Teflon PTFE, and carbon or aluminum oxide. A fundamental flaw doomed the tiny implant: It simply couldn't withstand the wear and tear of the lower jaw sliding on its Teflon surface. In some cases, it disintegrated within a few months.

The IPI fiasco has been ruinous for everybody involved. Vitek was forced into bankruptcy; Dr. Homsy is in professional entity in reach, has been ensnared in litigation, despite a disclaimer it sent Dr. Homsy in 1967 warning about medical complications caused by implanted Teflon-like polymers.

The First Implant

Dr. Homsy is one of bioengineering's pioneers. After earning a Ph.D. in chemical engineering at Massachusetts Institute of Technology, he spent seven years at DuPont in sales and as a Teflon researcher. In 1968 he developed Proplast, which gained wide use in plastic surgery, including chin and cheek implants.

In 1974, Dr. Kent began cutting implants out of sheets of laminated Proplast/Teflon (then being sold by Vitek for plastic surgery) and using them to cover the tips of jawbones in TMJ patients. Other surgeons followed his lead with good results, and some began using the sheeting to replace perforated disks.

By 1979, sponge-like Proplast was being touted by the American Association of Oral and Maxillofacial Surgeons as the "living implant" because human tissue could grow into its pores. At the group's annual meeting that year, Dr. Kent reported on the results of 50 jaw implants, saying that virtually all of the patients showed "marked pain relief and restoration of jaw movement," according to a press release.

At a major meeting of TMJ specialists three years later, Dr. Kent sensed booming demand for Proplast/Teflon. "We anticipate numbers of procedures to rise to 10,000 or more annually easily within the next year," he wrote to Dr. Homsy in March 1982. In the letter, he suggested producing precut disks in an "ovoid shape" so surgeons wouldn't have to do the cutting at the operating table.

FDA's Imprimatur

One year later, Vitek had the go-ahead from the FDA to market a precut disk, the IPI. To obtain FDA approval, Dr. Homsy merely had to persuade a bureaucrat that a Proplast/Teflon device was "substantially equivalent" to a product already on the market before the enactment of a 1976 law regulating medical devices. In this case, the product was an implant made of Silastic, or silicone rubber. Silastic implants have failed, too, but the consequences generally have been less severe.

Once approved, the IPI took off commercially, thanks largely to a timely boost from a trio of Tucson surgeons, one of whom had been taught by Dr. Kent how to use Proplast/Teflon in the TMJ. At an oral-surgery meeting in Berlin, Tucson surgeon Theodore Kiersch reported a 93% success rate – high for this kind of procedure.

This helped touch off what Dr. Kent later called "a stampede" among oral and maxillofacial surgeons to implant the IPI in TMJ patients. For them, it was a bona fide business opportunity, a chance to do more than wisdom-tooth extractions and root canals. "It became the fashion," says John Westine, a Delray Beach, Fla., oral surgeon. "Guys were putting them in

"We'll slip this little disk in, and you'll be out of the hospital in two to three days." The attending surgeon was Dr. Kiersch. It was the first of four major operations for Ms. Meyer, all unsuccessful, including a 1985 procedure by Dr. Kent, who replaced two IPIs with Vitek-made jaw joints.

Yet-another surgeon has since removed those joints and rebuilt her eroded jaw bones with grafts from her rib cage, leaving her in perpetual pain. "There are days when my jaws are so swollen and blue I can't open my mouth," she says. "I have to pack my face in ice and stay in bed, with the curtains drawn and the door closed. I need the quiet. I need darkness."

Scant Testing

Dr. Kiersch, looking back, feels betrayed by the implant's makers. "My duty was to find the best material possible," he says. "I'm a clinician; I'm not a research person. We were told the material had been released by the FDA. We assumed it had been tested in the animal joint."

Today, many medical devices undergo lab tests, animal experiments and human trials involving groups of closely monitored patients. In those days, however, such testing generally wasn't required of medical devices. Vitek never tested the IPI in animal jaws before marketing it. Vitek took the position that there was no way to reproduce in a lab animal what happens in the human TMJ.

The company didn't do any human trials, either. It relied on the early success that Dr. Kent and others had in implanting Proplast/Teflon in TMJ patients. While such limited, unstructured testing would never pass FDA muster as a clinical trial, Dr. Homsy contends it was an "effective" one.

Vitek did run tests on a mechanical simulator that imitates the human jaw. But the company never did the most obvious test of all: testing Proplast and Teflon together, as a laminated product, to determine how long the IPI would withstand the stresses from biting and chewing.

Stress Test

Mark Fontenot, a bioengineer who once consulted with Vitek on a physical-therapy device and who has done research with Dr. Kent, three years ago did such a test using a simulator patterned after Vitek's. He found that the machine, in sliding back and forth over the IPI with 20 pounds of force, wore through the Teflon surface into the Proplast backing 100 to 200 times faster than the wear-rate reported by Dr. Homsy. It fractured the thin Teflon layer, scattered microscopic Teflon particles all about and ate into the underlying Proplast. At that rate, according to a scientific paper Dr. Fontenot published last year with Dr. Kent, the IPI would have a "service life" of only one to three years.

How did Dr. Homsy err so badly? His wear-testing was of Teflon with a metal backing that didn't give way under the 20-pound load. Dr. Fontenot says. Had

porous Proplast isn't solid enough.

"It's like paper backed by a sponge," says Dr. Fontenot. "You can take a pencil and punch a hole in the [Teflon] surface. Almost anything would have been better than Proplast, even papier-mache."

Dr. Homsy says Dr. Fontenot's simulator test isn't representative because the implant was supposed to gain strength after implantation as body tissue grew into the pores of the Proplast. In most cases, however, "you don't get in-growth," says Barry Sands, a biomedical engineer and former FDA investigator who did a risk evaluation of the Vitek implants. Once implanted, he says, the IPI gets repeatedly compressed between the upper and lower jaws "like a carpet that binds up under a door," and the pores in the Proplast "get closed off."

Only after reports of IPI failure began rumbling in around 1984 were animal studies done. In 1984, a colleague of Dr. Kent's implanted IPIs in dogs. The results were "essentially catastrophic," according to a 1990 deposition that Dr. Kent gave in an Arizona court case against Vitek in Tucson. After just a few months, the Teflon layer was "completely worn" and Teflon particles had triggered bone erosion in the dogs. To Drs. Kent and Homsy, however, the test showed mainly that the dog wasn't a good test animal to use.

Monkey Jaws

The dog study wasn't the only one to be disregarded. In May 1986, Mohamed El Deeb, a professor at the University of Minnesota dental school, had Dr. Homsy come to Minneapolis to see the results of his experiments on monkeys. Both Proplast/Teflon and Silastic implants began to fragment after a year, causing "severe degenerative joint changes," but the reaction was more pronounced with Proplast/Teflon, says Dr. El Deeb.

He says Dr. Homsy made no comment. Asked about the study today, Dr. Homsy says that monkeys weren't a good model.

Reports of Vitek implant failures continued to crop up. The most alarming, published in 1986, involved a 37-year-old woman who had an IPI put in after having her jaw broken by her abusive husband. Teflon debris from the worn implant had migrated through her lymphatic vessels into lymph nodes in her neck, causing painful inflammations, according to researchers in Chicago. The IPI failed, they concluded, because it "couldn't withstand the loads generated" by chewing.

For Dr. Kent, this case was something of a turning point. Besides bringing it to Dr. Homsy's attention, he says he began "blowing the whistle" on the IPI, albeit indirectly. As chairman of scientific sessions at the Oral Surgeons association's national meeting in 1986, he gave IPI critics a chance to present papers.

Warning Letter

In October of that year, Vitek had no choice but to notify every member of the association about the increasingly obvious complications. Among other things, it said the prognosis for the IPI's success beyond three years was unknown. But Vitek blunted the letter's warning by also trumpeting the results of an oral-surgeon survey: 91.5% of 5,070 implant cases showed "satisfactory" results, it said, without defining "satisfactory."

By 1987, malpractice lawsuits against surgeons and product-liability suits against Vitek were mounting. Nonetheless, in July of that year, a Memphis surgeon suggested to Marcie Grossberg, a school librarian who had been hit in the jaw by a student, that she get IPIs. "The only Teflon I knew about was in my skillet," says Ms. Grossberg, 40, who says she trusted the doctor's assurances that the IPI was "state-of-the-art" treatment.

She shouldn't have. Within a few months, her implants were disintegrating and her chin was receding. "I couldn't get my teeth together," she says. "Food would fall out of my mouth." In October 1988, she found another surgeon to extract the implants. Now she suffers from immune-system disorders that doctors believe may be caused by unremoved Teflon particles.

Today, Drs. Homsy and Kent are squabbling over the testing issue. In a February 1990 letter, Dr. Kent says Dr. Homsy didn't do the "appropriate" animal tests "in spite of my suggestion in the early 1980s that they be performed." The next month, Dr. Homsy retorted: "You have repeatedly informed us that there were no appropriate animal models and that testing performed by you and LSU substantiated that conclusion."

Ownership and Royalties

Dr. Kent, nationally known as an innovator in reconstructive and oral surgery, is trying to distance himself from the entire catastrophe. "My role in the IPI was essentially nothing," he asserts, even though he advised Dr. Homsy on the implant's shape. Dr. Kent also owned a 1% stake in Vitek, and from 1984 on he got a 4% royalty on every TMJ product sold – about $50,000 a year, he says (Dr. Homsy pegs it closer to $100,000 some years). He got additional royalties on Proplast facial implants of his design.

As for Dr. Homsy, he sees the entire affair as a "holocaust" for himself, his family and his company, as well as for bioengineering and the medical-device industry. But he doesn't concede that the IPI was a misapplication of his beloved invention, Proplast, or that, as designed, it was inherently flawed. "Unfortunately," he says, "the implant is a set piece for scapegoating."

Instead, he blames not only surgeons but also patients, for failing to follow their surgeons' post-operative admonitions against opening their jaws wide or eating solid food until they are fully healed.

Throughout all this, the FDA seems to have missed several opportunities to intervene and head off the IPI disaster. The initial inspections of Vitek's plants after the IPI was approved in 1983 were limited and failed to uncover any significant problems. It wasn't until July 1988 – one month after the company pulled the product off the market – that the agency conducted a comprehensive inspection of Vitek's plant. That inspection, which included checking quality controls and other manufacturing practices, turned up numerous violations.

Red Flags Waved

FDA officials say Vitek wasn't relaying all of the reports it was receiving of problems with the devices, as it was required to do. But the FDA also was unaware of or failed to act on several other signs that something was seriously amiss, including the company's 1986 letter to surgeons and a 1987 report from the U.S. Air Force about implant failures, severe pain and bone erosion. Complaints from air bases prompted a notice to every branch of the armed services cautioning surgeons against using the IPI. But the government didn't recall the product until December 1990. Says Henry Wall, a Norcross, Ga., oral surgeon: "The FDA was asleep at the switch."

FDA officials contend that the agency acted as soon as the problems came to the agency's attention.

For most patients whose implants have failed, there are few alternatives. Two companies – TMJ Implants Inc. of Golden, Colo., and the Northeast Dental Center of Los Angeles – are marketing jaw implants, both of which were on the market before 1976 when FDA approval wasn't required. (They are different from the interpositional disks and are made of metal, not Proplast or Teflon.) Both companies claim good results with their implants. Some surgeons recommend using patients' own tissue to reconstruct the jaw joint, but such surgery often fails as well.

What's more, every medical option is very costly. Many IPI patients are destitute, having lost their jobs and exhausted their savings and insurance coverage. And others are stymied by coverage limits.

Arlen Huber, 35, suffers from facial swelling and severe headaches and wants the IPI he received after a farming accident taken out. The lowest surgeon's estimate the Fingal, N.D., farmer can get for doing so is $25,000, not counting anesthesia or hospitalization. But under a 1989 state law, insurance carriers can limit lifetime coverage for surgical treatment of TMJ disorders to $8,000.

Mr. Huber says he has appealed to state officials in Bismarck for help, but "they can't do anything for me."