

Cutting-edge implant helps patients see clearly

September 23 2013, by Nichole Brochu

A Sunrise, Fla., surgeon is among the first in the nation to perform a stitch-less implant in the eye to correct both acute myopia and astigmatism, a debilitating pair of conditions that afflict millions of Americans.

The device, called the Ophtec Artiflex Toric Lens and manufactured by a Netherlands-based company with U.S. offices in Boca Raton, Fla., does not yet have Food and Drug Administration approval. But the FDA has afforded Dr. Andrew Shatz a rare "compassionate use exemption" to implant the silicon lens in the eyes of three patients.

Confident that the southern Florida region is home to "several thousand" similarly vision-impaired patients, Shatz is hoping to identify 200 of them for a possible clinical study that could speed up the FDA's approval.

"There's no alternative for these patients," Shatz said. "They can't wear contacts (well). They can't use glasses because it causes too much distortion. And they're not candidates for Lasik ([corrective surgery](#))."

That was the predicament that Deerfield Beach, Fla., native Jennifer Burke, Shatz's first Artiflex Toric implant patient, found herself in.

At 25 years old, she's been through a lifetime of ill-fitting glasses and contacts, none of which gave her even near-perfect vision. Because of her severe [astigmatism](#), which distorts the shape of the eye, she also had

several contacts pop out, once while driving. "I never felt confident wearing contacts," she said.

Now that she's determined to join the Navy, Burke needed a better solution to meet the military's vision requirements. Two weeks after Shatz implanted the Artiflex in both eyes, Burke can't believe the difference in her life.

"I can go swimming, I can go on a roller coaster and not be afraid they'll blow out of my eyes. It's like a brand-new world," Burke said of her 20-25 vision post-surgery. "Even if I change my mind about the military, this gave me peace of mind to be able to see."

The procedure didn't come cheap. Because it's not FDA-approved, insurance won't cover it. Shatz estimated the implants, which must be done separately for each eye, cost at least \$5,000 per eye. Burke took out a credit card to pay for hers, calling the two procedures "my No. 1 priority."

Lenses like the Ophtec Artiflex Toric have been widely available in Europe and Asia for years, where studies have shown them to be highly effective in treating severe cases of myopic astigmatism, according to the *Review of Ophthalmology* medical journal.

Now, two U.S. companies - Ophtec here and STAAR Surgical in California - are seeking the FDA's nod for these "foldable" lenses. Unlike other implants, like those for cataracts, these do not replace the eye's natural lens, but instead are laid over them to correct the distortions.

Shatz, the only U.S. surgeon who has implanted Ophtec's lenses, said the foldable design is key. While prior implant lenses are made of hard plastic, these are soft, like daily contacts, so they can be folded into a

much smaller incision that doesn't require stitches to close.

The implant procedures, then, can be performed in less than 15 minutes, under local anesthesia where the patient is awake the whole time, and the recovery time is minor, the doctor said.

After removing an overnight patch the morning after each surgery, Burke said the difference in her sight was immediate. "I could see clearly," she said. "I was shocked."

Bringing the lenses to the U.S. market, though, remains a challenge since the FDA does not yet have enough studies to complete its review, Shatz said.

That's why Shatz, the lead surgeon at SightTrust Eye Institute in Sunrise, Fla., is hoping to recruit a couple hundred local patients so he can persuade FDA officials to sanction a study in the hopes of demonstrating how "safe and incredibly effective this is," he said. To qualify, patients between the ages of 18 and 45 must have more advanced near-sightedness complicated by astigmatism and have difficulty seeing and functioning with glasses and contacts.

Florida Keys resident Devon Spaulding, 26, had his left eye implanted with the Artiflex and will have Shatz do the right eye later this month. A smart-home system installer by day and musician by night, Spaulding said the dusty, smoky environments had made his already ill-fitting contacts almost impossible to wear.

"This was my only option," said Spaulding, who has worn glasses since kindergarten and contacts since the third grade. "I really didn't have any other choice."

More information: If you believe you are a candidate for Shatz's

potential study, call the SightTrust Eye Institute at 877-878-7890.

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