

The original “knife”

Initially Radial keratotomy, and now excimer lasers that can restore the cornea in 5-10 minutes, make myopia just a memory. This seems to be the modern myth of science and technology.

LASIK, by far the most common excimer laser refractive surgery, has spread across the world over the last 20 years with more than 30 million patients seeking to see the world without glasses. But questions of accuracy, security and stability still linger. Is LASIK really worth it?

A 2012 Valentine! Taiwan Taipei University Professor CAI Rui-Fang announced this week that he will no longer perform LASIK. CAI Rui-Fang pioneered the LASIK procedure in Taiwan introducing it to the island in 1995. He is abandoning the procedure because some of his patients are experiencing marked decrease in visual acuity years after the procedure. Chinese Eye Hospital stocks dropped on news of this denouncement.

According to CAI-Ru-Fang, LASIK was the first laser eye surgery procedure to utilize a flap. Initially a lamellar knife was used. Now a knife-free laser known as a femtosecond laser is used to create the flap. Once the flap is created, the tissue under the flap is sculpted with a laser to make the desired degree of correction, and then the flap is put back. “In the past our industry thought the restoration of the corneal flap was very strong”. This has not proven to be the case. In just the past few years CAI-Ru-Fang has treated four patients with dislocated flaps. According to Ru-Fang, this demonstrates that strong healing of the cornea does not take place after LASIK, and that the flap can be lifted or dislocated long after the original procedure. In addition, CAI-Rui-Fang has found that some people who have had LASIK surgery done after the age of 40 or 50 experience a loss of vision after surgery that cannot be corrected with glasses even in the absence of other eye diseases like cataracts or glaucoma (The FDA uses the term loss of best corrected spectacle vision). Careful examination of these patients eyes reveals they have allergic inflammation or chronic dry eye syndrome. Is this is not bad enough? There are also the unknown risks, CAI-Rui Fang said.

Victims are not alone. The promise to “throw away his glasses” and the knowledge that US Navy was using this technology on their troops, was too tempting for Wang Muqing. He underwent LASIK surgery for his myopia at Shenyang Aier Hospital on Feb 18, 2010. Wang reports most people cannot imagine what he sees. His mobile phone charger is not a red point of light; it

is a dazzling display of starbursts and glare. He experiences ghosting where figures overlap. He has painful dry eye that prevents him from working overtime at night. "It has ruined my life." Wang says. Wang Muqing is not alone. Yang Ming had his surgery at Taiheng eye Hospital in Chongqing in 2005. Ming developed irregular astigmatism. Other patients report similar findings such as glare, ghosting and dry eye pain that never goes away. How many such victims there are in China is not known, as there are no official statistics being kept.

Across the ocean in the United States, there is already a cause for action against LASIK. Todd Krouner a medical litigation attorney in the United States reports that since 2005 he has already helped 20 patients recover damages as a result of poor LASIK outcomes. He reports that one of his patients who became disabled from his job as a Wall Street Banker received a \$7.25 million malpractice award.

Dr Boshnick, OD who treats many patients with post LASIK complications in the US reports, "My feeling is that the number of post-LASIK patients in North America who have been suffering adverse events due to LASIK is over one million. Being conservative, about 5% of patients who have had LASIK are suffering significant loss of quality vision and ocular discomfort. Please understand that studies of patients who have undergone LASIK have not gone beyond one year. Most of the patients I am seeing encountered their vision loss 2 to 8 years after having undergone this procedure. My gut feeling based upon my discussions with patients who have undergone LASIK is that at least 30% of patients wish they had not had it done. From what I have seen, I believe LASIK is a major public health crisis."

CAI Rui-Fang is not the first to say no to the insiders. In 2010 famous Japanese LASIK surgeon Professor Qingshuigong, Director of ophthalmology at the University in the North went public with his admonition to patients to never have LASIK surgery. It was vision problems occurring six to eight years after the procedure that convinced him to call for a stop to the procedure.

On January 6, 2011 Morris Waxler, PhD, who was the division director at the CDRH at the FDA who oversaw the approval of excimer laser for LASIK in the United States, filed a petition with the FDA asking that FDA withdraw its approval of all devices used for LASIK. Waxler states, "All surgery has benefits and risks and so does LASIK. The benefits of LASIK are trivial: a temporary improvement in refraction. The risks are permanent including but not limited to a misshaped and sick cornea with haze, loss of contrast sensitivity, cornea pain, itchiness, ectasia, corneal transplantation, and

suicide. Corneas treated with LASIK are free of disease and made sick by LASIK. LASIK manufacturers, clinics, surgeons, and FDA falsely tell clients that 12 months and longer after surgery they have <1.0% risk of corneal problems. FDA's own records show that the adverse event rate from LASIK is about 20.0% 12 months after surgery. The LASIK-medical-industrial-FDA complex is suppressing the true risk of LASIK-induced ectasia and corneal transplantations, which probably exceeds 1.0% ten years after LASIK. The FDA has acknowledged receipt of Dr Waxler's petition on their website

<http://www.regulations.gov/#%21documentDetail;D=FDA-2011-P-0022-0002> and has indicated that they have not yet been able to make a decision. Essentially, Dr Waxler says, the FDA is ignoring his petition. According to Waxler, LASIK surgeons are not healers. They are "corneal cosmetologists" that create pain, suffering, and needless risk of corneal transplantation and blindness.

Southern Weekly reporters contacted China's 12 largest hospitals that perform LASIK for the treatment of myopia. Reporters found that almost all hospitals minimized surgical risks or were vague about what the risks were. All hospitals insisted that there has never had a bad LASIK outcome.

Laser surgery for myopia is just beginning to see rapid development in the Chinese market. Many hospitals in China want to become a part of this large myopia treatment market. A Ministry of Health/Ministry of Education joint survey's latest data show that there are more than 400 million Chinese patients with myopia, or approximately one third of the Chinese population. In China, only 0.18% of the patients eligible to have this procedure have had it. Currently LASIK surgery costs between 2000 to 15,000 Yuan. Aier Eye profit margin is currently at 70% ranking it first among all medical services. Under rapid expansion of the market, appropriate regulation to assure patient safety is not in place. With all kinds of confusing propaganda, self-regulation by the industry itself is not enough.

Laser eye surgery can work well when nothing goes wrong, we should not ignore the fact that the corneal flap never heals. There is the creation of a new structure that can create some yet unknown pathology. What kind of problems we will encounter in the future are not known, so we should be telling patients about these risks, CAI Rui Fang said.

Wang Muqing still seeks answers to his suffering. He has gone to countless hospitals looking for a solution. Finally Aier Hospital was willing to compensate him for tens of thousands of dollars, but he did not accept. He

wants his old eyes back. To protect the privacy of the interviewee, Wang Muqing and Yang Ming are pseudonyms)