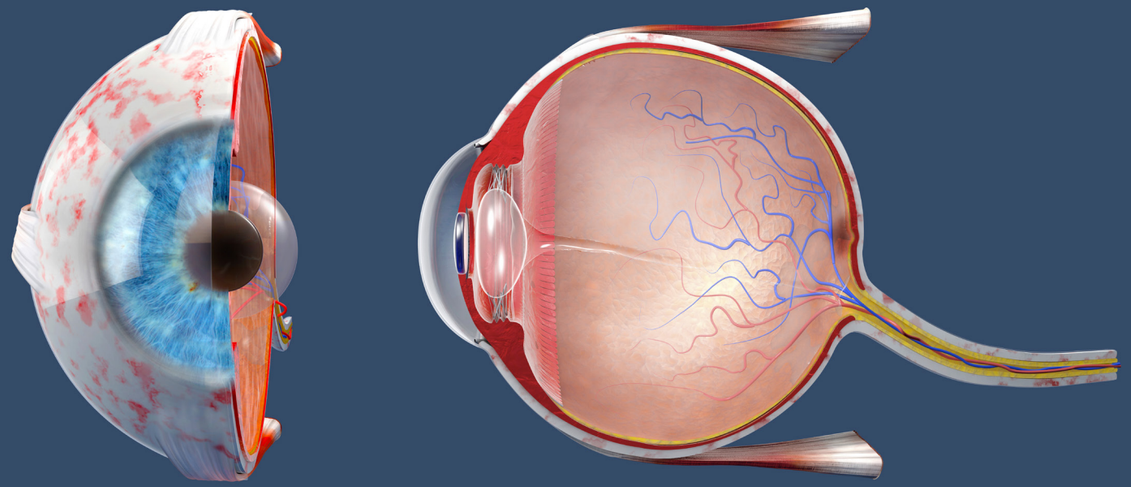


The eye's natural lens can be seen here as the clear disc-like structure at the centre front of the eyeball, behind the pupil and the iris.

Christoph Burgstedt/Science Photo Library/Getty

IMPROVING IMPLANTABLE LENSES TO TREAT MYOPIA

REFRACTIVE LENSES IMPLANTED in the eye are being increasingly used in China. A medtech company and a university are now teaming up to further improve designs.

Myopia, or nearsightedness, is common globally, but in some parts of east and southeast Asia rates are extremely high, affecting 80-90% of young people. A university in China is now collaborating with a biotech company to develop potential new solutions.

Myopia occurs when elongation of the eye axis causes light to focus in front of the retina instead of on it, making distant objects look fuzzy. Glasses may work as a solution for some people, but the lenses required may be unacceptably thick for people with severe myopia. Contact lenses are also an option, but they need to be frequently replaced. Another alternative, corneal laser refractive surgery, also doesn't work in cases of severe myopia, or for people with thin corneas.

An increasingly popular alternative in China is a special type of implantable refractive lens called a phakic refractive lens (PRL), suitable for patients with high and ultra-high myopia.

PROBLEM SOLVING

Several types of implantable refractive lenses have been approved by the China National Medical Product Administration, the U.S. Food and Drug Administration and similar bodies in other jurisdictions. To date, PRLs only have been approved in China, where two types are now in use. Those devices are implanted under local anaesthetic, and are intended to be left in the eye permanently. Occasionally, they need to be removed due to other eye surgeries or complications, such as glaucoma. That requires more surgery, and may damage the eye.

Haohai Biological Technology, a Shanghai-based company that develops and manufactures, and sells biomedical materials and PRLs, has teamed up with Fudan University, to improve the performance of PRLs and reduce the possibility of complications.

Haohai is also working to improve the procurement of quality raw materials and developing manufacturing innovations in the field of ophthalmology.

Such collaborations between academia and industry can benefit the development of medical devices, says Jianguo Sun, who leads the Fudan University side of the project and is based at Eye and ENT Hospital in Shanghai.

"Research institutes can propose and verify solutions," says Sun, "and industry can scale up and standardize production, and advance marketing and clinical application."

Haohai has more than a decade of experience in biomedical materials, particularly for ophthalmology. This expertise covers products for cataracts, myopia prevention and control, and treatments for diseases of the retina such as retinal detachment.

PRLs are manufactured from silicone materials that are highly elastic and hydrophobic. They are implanted in the space between the iris and the lens, and are suspended in the aqueous humour, a watery fluid that circulates through the eye, providing nutrients and keeping the eye inflated.

But PRLs can block circulation of the aqueous humour, altering pressure in the eye, which the researchers suspect leads to complications such as glaucoma. Currently, doctors in China make one or two iridectomy holes before or during implantation to allow fluid to move more freely between different parts of the eye. However, this also increases treatment time, cost, and the risk of complications.

NEW DESIGNS

Haohai's researchers and Sun are working together to prevent such a problem. One of their designs is a series of grooves on the outer portion of the PRL. These grooves could allow the aqueous humour to flow through the pupil to maintain uniform pressure, without affecting the optics of the lens.

To test the safety and effectiveness of the grooved lens, Sun's team and Haohai's researchers ran a series of tests on three different PRL designs: the new lens, 'LG-PRL', with grooves surrounding the central optical zone; and two original PRLs — one the same size as LG-PRL, and one suitable for smaller eyeballs.

The researchers implanted the three types of lenses into the eyes of rabbits. At two weeks, they measured intraocular pressure in the three groups of rabbits that received a PRL, as well as a control group that did not receive an implant.

"Our animal experiments show that the new PRL product did not increase intraocular pressure in rabbit eyes. This indicates that the PRL product allowed the free flow of aqueous humor, from the posterior chamber to the anterior chamber, solving a core issue," says Sun. The results were published in the journal *International Ophthalmology* in 2022[1].

The two teams of researchers are working to further refine LG-PRL to produce a next-generation lens that could offer improved vision in dim light, and is suitable for milder myopia. To achieve this, the researchers will require more experimental results from visual function research in humans, adds Sun.

Meanwhile, the current version of LG-PRL, called PRL-S5, is being tested in a two-year clinical trial to evaluate its efficacy and safety in humans. The work is led by Fudan University's Eye and ENT Hospital, and involves collaborations with five leading ophthalmology departments from across China, such as The First Affiliated Hospital of Zhejiang University School of Medicine; Zhongshan Ophthalmic Center, affiliated with Sun Yat-sen University in Guangzhou; and West China Hospital of Sichuan University.

Beyond collaborating with scientists such as Sun, Haohai is also focused on earlier stages of the biomaterial production chain, such as raw materials and their preparation.

BETTER RAW MATERIALS

In 2017, Haohai acquired Contamac, one of the world's largest suppliers of raw materials for implantable lenses, ensuring a stable supply.

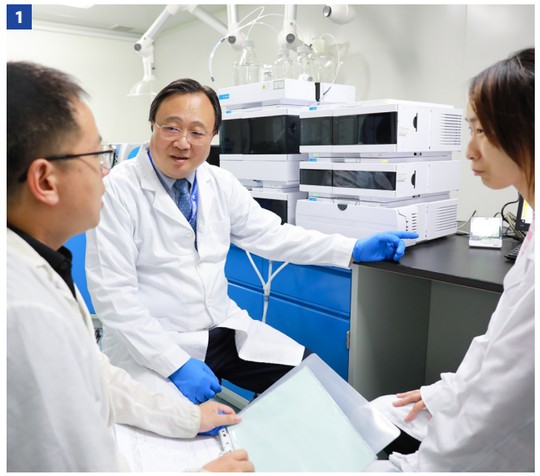
"We can only produce market-competitive intraocular lenses of optimal quality if our raw material is optimal," says Jianying Wu, executive chairman and general manager of Haohai Biological Technology.

Another focus for the company is how lenses are manufactured. The traditional process involves several steps, including grinding, polishing and cutting. This multistep process increases the risk of error and wasted material.

To address this, Haohai acquired a local company, Henan Universe, that has developed a one-step moulding technology.

"This technology injects raw materials into a mould to create lenses with improved accuracy, production continuity and productivity," says Wu.

Our work is always led by the patient and their clinical needs, says Wu. "To address those needs, we anticipate collaborating with more domestic and international universities, research institutions, and companies to accelerate technical innovation," he says. ■



▲ 1. Jianying Wu (second from the left), Haohai's executive chairman and general manager, discusses product development with the R&D team.
2. In the workshop, Wu (left) discusses with a production expert how to transform research results into products and control quality.

REFERENCE

1. Zhang, S., Huang, C., Miao, H. *et al. Int Ophthalmol* **42**, 3459–3468 (2022). https://doi.org/10.1007/s10792-022-02345-y

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