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XENIA: A Natural Solution

Experts discuss six years of keratoconus treatment with the XENIA corneal implant

The XENIA lenticule is a single-use, disc-shaped corneal stromal implant manufactured from purified porcine corneal tissue, available in different thicknesses and profiles. XENIA implants are used to avoid corneal transplantation in patients with keratoconus or to defer corneal transplantation as long as possible. For keratoconus the implant is crosslinked and is therefore significantly stronger than the patient's own stroma, thus stabilizing the cornea. The procedure is reversible, and the lenticule can be removed in cases of intolerance or complications.

For patients suffering from advanced keratoconus, DALK surgery (deep anterior lamellar keratoplasty) has been the surgical solution of choice in order to prevent corneal blindness. However, DALK surgery is very complex, requiring general anaesthesia and corneal sutures, and it comes with the risk of graft rejection.

There is also the issue of donor tissue availability. As John Marshall, Emeritus Professor of Ophthalmology, Institute of Ophthalmology, University College London and Emeritus Professor of Ophthalmology, King's College London, points out, there are only two countries in the world which have sufficient human donors for corneal transplantation: US and Australia. As for the rest of the world, "there's absolutely no way with current donor rates that the demand could be satisfied."

XENIA, however, looks to natural evolution for a solution. "500 million years ago, fish had corneas, their corneal structure is almost identical to the structure of the cornea that we see in vertebrates today and this also implies continuity of genes" says Marshall. Looking 'closer to home' at mammals, pigs in particular, "it is relatively easy to preserve the architectural structure of the stroma when using pig tissue for the cornea," Marshall explains. "The tissue needs to be cleared of cells then the stromal collagen compressed to combat swelling and cross-linked to stabilise. This creates a biological implant that can be used for transplantation into human corneas." This follows a precedent whereby pig tissues have been successfully implanted in humans for many, such as heart valves .He adds, "Given that around 260 million pigs are slaughtered in the European Union every six months, there's absolutely no shortage of donor tissue."

Clinical studies

XENIA implants were first used in 2019 in eyes with advanced keratoconus, particularly those with keratometry (K) readings above 68.00 diopters and considered ready for DALK.

"Increasing the thickness of the cornea through tissue addition offers treatment options for patients who may otherwise be unsuitable due to extreme corneal thinning," explains Ahmed El-Massry, Professor of Ophthalmology, Alexandria University, Egypt. "Altering the biomechanical properties of the corneal stroma may help stabilize the cornea and slow the natural progression of keratoconus, potentially postponing or avoiding the need for corneal transplantation."

The first clinical study of XENIA was presented at the ESCRS Winter Meeting in 2019 (1). "During a follow-up period of up to six months, all treated eyes demonstrated stable outcomes with clear lenticules. Six of the seven eyes showed improvement in corrected distance visual acuity (CDVA)," says El-Massry (2). Although the implants provide mechanical support to the cornea and induce changes in corneal thickness and anterior curvature, they do not alter the intrinsic collagen stiffness of the cornea. "As a result, corneal collagen cross-linking was performed three months after implantation in all cases to reinforce corneal biomechanics."

A long-term follow-up study (60 months) on the same seven eyes confirmed the safety and efficacy of these lenticules in corneal flattening, visual improvement, and absence of immunological reactions, El-Massry adds. "Overall, implantation of the first-generation XENIA lenticules under the SMILE cap resulted in visual improvement in six out of seven eyes after one year and maintained visual gains for five years post-intervention (3).

Ease of implantation

For Mohamed Hosny, Professor of Ophthalmology, Cairo University, Egypt, the XENIA implant stands out in terms of ease of implantation. While the lenticule is sophisticated in its architecture, its design, and its biological characteristics, "implantation is straight forward," he says. "This should encourage more surgeons to adopt the technique, and unlike other surgical options like DALK, it will not be limited to high end tertiary corneal surgical units."

The procedure involves the formation of a femtolaser-assisted pocket in the corneal stroma. "The pocket should be wider than the lenticule size by 1 mm, and as deep as possible," says Hosny. "Since in keratoconus the central corneal thickness can be low, the usual recommendation is to plan the pocket 150 µm above the Descemet membrane, and to make sure that it is more than 250 µm in depth. The use of a femtolaser machine with a real-time OCT capability make this very easy."

"The wow effect"

Mohamed Shafik Shaheen, Professor and

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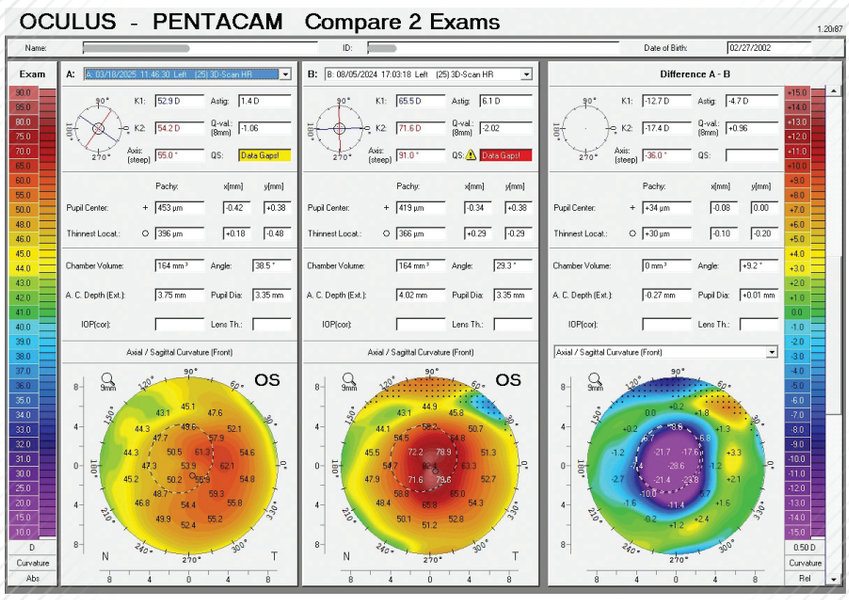

Figure 1.

Head of Ophthalmology at Alexandria University, Egypt, and Vice President of the International Keratoconus Society (IKS), highlights successes from recent cases of advanced keratoconus (9 eyes: eight months' follow-up; 16 eyes: four months' follow-up) where XENIA was implanted "in a deep pocket, 210 to 220 µm from the surface." All cases showed a significant improvement from the first week in the level of corneal flattening, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) and decrease of negative high Q-value.

Shafik points to XENIA's "wow effect" in one patient, particularly, resulting in 11 diopters of central flattening with regularization of K-readings between upper and lower cornea over two months. There was also an improvement in the patient's UCVA from 0.2 (pre-op) to 0.9 (post-op), with a significant decrease of coma and spherical aberration. This improvement has been maintained over eight months of follow-up, Shafik adds. He also highlights that in some cases of an extremely high Kmax (over 65 diopters), XENIA implants have resulted in "a significant central flattening, with accompanying improvement of both UCVA and BCVA." (Figure 1 shows a patient with a central fattening of 28 diopters, maintained over three months of follow-up.)

"The strong flattening ability of XENIA results from the effect the stiff implant on the distorted posterior corneal surface, pushing it backwards and regularizing it, thus having a positive impact on the higher order aberrations and visual acuity," explains Shafik. He adds: "The implant opens the way towards treating advanced keratoconus and ectatic disorders, providing a tool for visual rehabilitation without having to do a form of corneal implantation. It gives new hope for advanced keratoconus cases."

Clear advantages

"While there are companies creating artificial corneas, I've always been intrigued by the amount of time, effort, and money that has been spent on this technology when we have an alternative like XENIA," says Marshall. One of the obstacles surrounding artificial corneas, for example, is getting regulatory approval, which has proved to be "a very protracted process." XENIA, however, has received regulatory approval in Europe, the UK, India, and Turkey. "It is an approved system," Marshall concludes. "So why go to all the bother of artificial corneas when there are hundreds of millions of years of evolution to draw on for a natural solution? I am a great believer in taking the low-hanging fruit!"

References

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3. *A El-Massry et al., "Safety and Indicative Effectiveness of Porcine Corneal Lenticular Implants in Patients with Advanced Keratoconus and Post LASIK Ectasia: A Retrospective Clinical Study," Clin Ophthalmol., 15:3165 (2021). PMID: 34345164.*

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