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XENIA Corneal Implant: A Sensible Alternative to Corneal Transplants for Keratoconus Patients

Experts outline the surgical benefits and improved patient outcomes using XENIA corneal implants for keratoconus


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XENIA is a corneal implant which uses corneal collagen from pigs. The lamella structure of collagen in corneas is ubiquitous throughout the animal kingdom, with the exception of some elasmobranchs, i.e., sharks and rays. One could say that it has been successfully validated by Mother Nature over hundreds of millions of years. Indeed, as John Marshall, Emeritus Professor of Ophthalmology, Institute of Ophthalmology Faculty of Brain Sciences, UCL, London, points out, "the first cornea with today's structure was in a fish – 580 million years ago. When nature gets something right, it sticks with it."

With pig corneas, Marshall explains, "You're dealing with an architectural structure identical to that of humans." And when this material has undergone the process of decellularization to remove cells and antigens, "you are left with a biologically pure, non-immune-response generating system." After washing and compressing, the material undergoes a proprietary crosslinking process which stabilizes it. Thus, the material's natural lamella infrastructure is preserved together with its transparency while its biomechanical properties may be enhanced, Marshall adds.

XENIA implants are used to avoid corneal transplantation in patients with keratoconus or to defer corneal transplantation as long as possible. Being significantly stronger than the patient's own stroma, XENIA stabilizes the patient cornea and regularizes the patient corneal topography, flattening the cornea, as well as reducing higher order aberrations.

XENIA in practice

Mr. Marwan Ghabra, Senior Consultant Ophthalmic Surgeon at Barts Health NHS Trust Whipps Cross University Hospital, London, and Mr. B. Ilango, Royal College Certified Laser & Multifocal Lens Implant Specialist at Wolverhampton Eye Infirmary, UK, are practicing surgeons with first-hand experience of using XENIA implants.

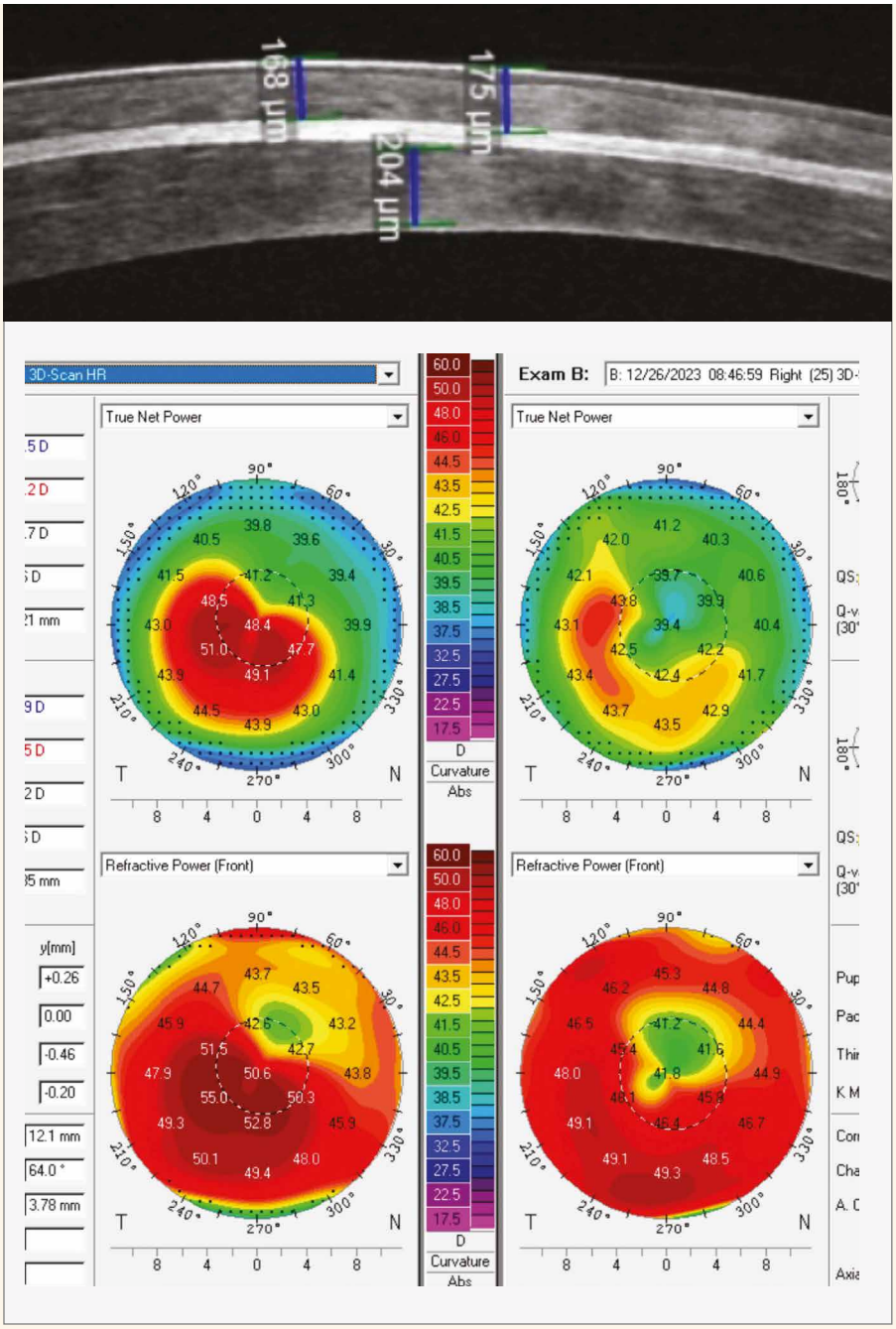
As an ophthalmologist focused on improving outcomes for keratoconic patients, Ghabra has spent many years in developing and refining new techniques. One of these is the Ghabra Technique, which involves the use of a XENIA intracorneal implant to create safely located, deep corneal pockets to address and reduce irregularities in the posterior and anterior corneal surface. "This technique has since become my preferred method for pocket creation and ensures that the pocket is created at the optimal depth for each individual, enhancing the overall effectiveness of the procedure," he explains.

"You've got exactly the structure you want, and you can manipulate the biomechanics to the strength that you want."

Having treated keratoconus patients with many surgical techniques over 20 years, Ilango praises the XENIA corneal implant for its biological material, easy availability, and cornea flattening properties. With XENIA, "the surgery can be done under topical anaesthesia and takes 15 to 30 minutes," he explains. "Femtosecond laser pocket creation makes the dissection very predictable and neat, while the XENIA implant, being a biological material, blends into the patient's corneal stroma." Ilango adds that no rejection has been reported and, since it "restores near-normal anatomy to the centre of the cornea, the visual improvement can be remarkable."

Following a XENIA implant, "all my patients have been satisfied to varying degrees and can get on better with their life due to improved best corrected vision," adds Ilango. "Version X4 of the implant is particularly promising," he goes on. "One of my recent patients is still 'over the moon' with her unaided visual improvement to better-than-driving-standard within 48 hours post-surgery."

Ghabra also notes that his patients have also shown significant improvements in visual acuity and corneal stability, "reducing the need for more invasive procedures such as corneal transplants." He adds, "The use of the XENIA implant not only addresses the immediate structural issues but also provides long-term benefits. In conjunction with the Ghabra Technique, it has shown



an average drop in Kmax of 15 dioptres. It represents a practical advancement in our ability to manage keratoconus more effectively and with fewer complications."

Unlike many other corneal procedures that are subtractive (taking away material from the cornea), XENIA is additive. "The lenticule is placed within the body of the stroma; I call this stromal supplementation surgery," says John Marshall. "For me this is great, because having produced and patented the Excimer laser for corneal laser refractive surgery I guess I've been one of the 'culprits' in weakening the cornea for 30 or 40 years. I was looking for something that would strengthen the cornea and indeed these lenticules have the potential of refractive surgery by addition, not subtraction. In keratoconus surgery, the idea is to put in a "stromal splint" to compensate for the loss of biomechanical properties in the host. With this more sophisticated XENIA technology, we can actually use these implants not only to stop the conic bulge, stop the biomechanical disturbance, but at the same time begin to correct the refractive properties."

The XENIA implant is reversible and exchangeable. If the patient's vision or corneal situation changes over time. the implant can be exchanged with another one that is better aligned with the new corneal or visual situation of the patient. Moreover, the XENIA implant is custom-made. Unlike the vast majority of ophthalmic implants that are mass-manufactured to pre-defined standards, it can be tailored individually to be perfectly aligned for the individual need of the individual patient.

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Quality and reproducibility

Tissue of porcine origin has been routinely used in surgery for more than 30 years – for example, in patients needing heart valve replacements. Further, says Marshall, "pig skin is used on burns victims, whole pig organs have been transplanted, and researchers are now looking at porcine pancreatic cells for diabetes." Where sourcing human donor material is difficult, there is no such problem with pigs, given the hundreds of millions that are routinely farmed in Europe alone. Around the world, "there are millions of individuals that need some kind of corneal transplantation surgery, but can't access it because of the shortage of human donor material, particularly in low- and middle-income countries," says Marshall. And in many places, the financial and access challenges associated with human corneal donations are compounded by religious or cultural pressures that stop people donating material.

"With the pig tissue, you've got exactly what you want," says Marshall. "You've got exactly the structure you want, and you can manipulate the biomechanics to the strength that you want." The XENIA implant now has regulatory approval in Europe, the UK, and India, and has been used in almost 200 implants in human eyes with no significant complications or immune responses. "All this is a good measure of the quality and reproducibility of the product."

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