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> **“...a pocket is created in the anterior corneal stroma using a femtosecond laser and then a customized implant is inserted into the pocket”**

XENIA IMPLANTATION - GHABRA TECHNIQUE

BACKGROUND

Keratoconus is a common corneal ectasia characterised by progressive thinning, steepening, and bulging of the central and paracentral cornea, resulting in visual loss. The Xenia implant is a medical device used in the treatment of advanced keratoconus and is fully compliant with the latest EU Medical Device Regulation MDR 2017/745. The treatment itself is simple: an anterior stromal pocket is created in the cornea using a femtosecond laser and then a customised implant is inserted into the pocket. This stabilises patient corneas, regularises corneal topography, reduces higher order aberrations, and, ultimately, improves vision. As such, the procedure offers an attractive alternative to corneal transplantation in patients with advanced keratoconus.

The procedure is additive and reversible; unlike subtractive and irreversible procedures, such as EXCIMER laser in refractive surgery. As the implant increases the thickness of the recipient cornea, it enables corneal collagen crosslinking (CXL), which may not have been possible otherwise. The implant material is stiff; with greater stiffness than human donor organs,resulting in greater corneal conFiguretion, fewer higher order aberrations, and better visual acuity after surgery. Unlike other implants, which are constructed from plastic or metal, it uses natural collagen, which is well tolerated by patients. As the implant is made from biological collagen, there is also potential for it to integrate into the recipient cornea. The implant is custom-made for each individual and manufactured to prescription. Figure 1 shows a slit-lamp image just one day following the implantation.

Figure 1 - Slit-lamp picture one day after lenticule implantation shows clear cornea

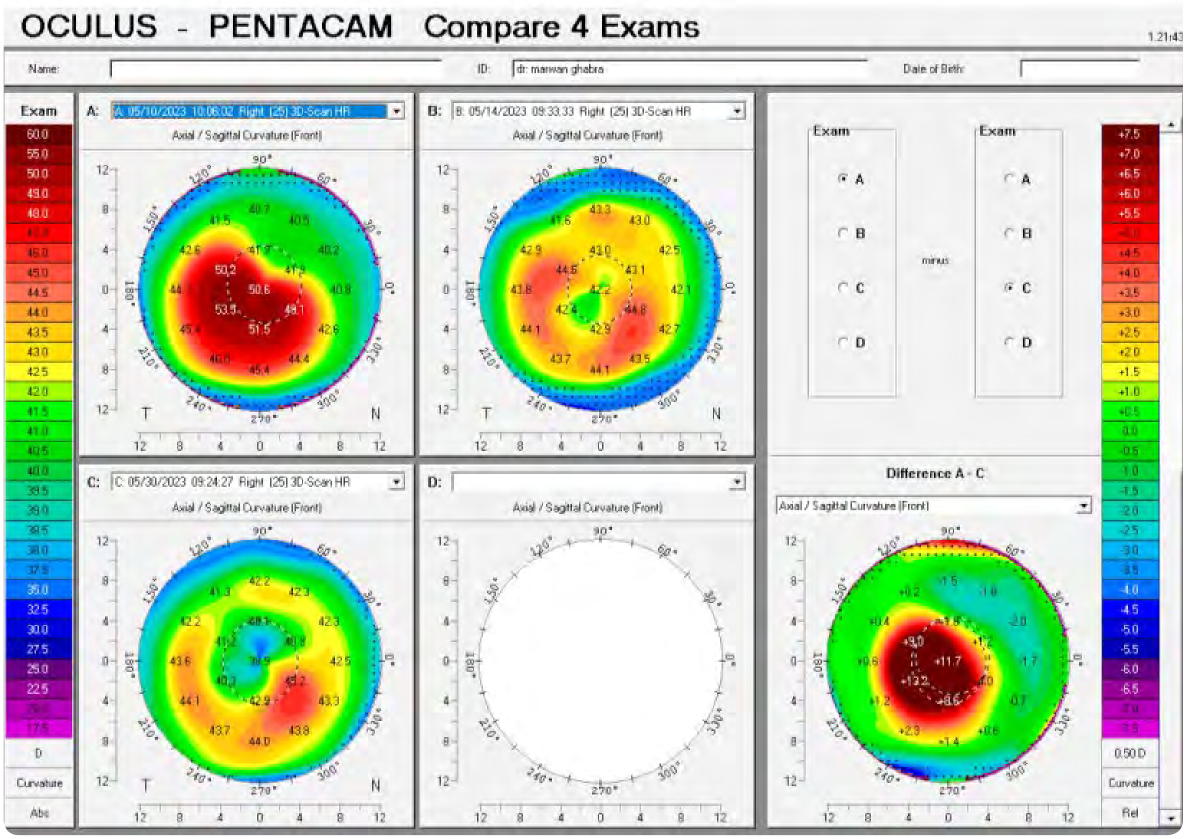

Figure 2

A study from 2019 showed that 90% of patients with keratoconus who received the Xenia implant experienced an improvement in their visual acuity. The implant works best for patients with advanced keratoconus who have no scars or previous hydrops. It is not recommended for patients with: early keratoconus who would be better treated with CXL; moderate cases that need CXL and intra-corneal ring segments (ICRS); or very advanced cases with broken endothelium or corneal scars.

My experience using the Xenia implant to date has been highly encouraging. All of my previous cases underwent CXL at least one year prior to receiving the implant. Following implantation of the lenticule, I have observed increases in average corneal thickness from 400 µm to 481 µm and decreases in anterior corneal astigmatism from 5.4 D to 3.0 D. Minimal changes were observed in average optical K readings, back elevation, back tangential curvature, and higher order aberration before and after treatment. I have observed improvements in both unaided and best corrected visual acuity, with stable vision at one year in all patients and none requiring corneal transplantation. Corneal topography measurements from patients who have now reached the three year mark show stable increases in corneal thickness with no significant changes in front and back elevation nor front and back keratometry.

The original procedure as described by Gebauer was to use a femtosecond laser to create a pocket at a depth of 130–200 µm from the anterior corneal surface. However, there are two limitations to this technique. Firstly, the relatively anterior depth of the pocket, decided based on the assumption that this would be safer, in patients who have already undergone CXL, and consequently have already had their corneas stiffened, means that the benefits of the Xenia implant are limited to an increase in corneal thickness, without significant change in anterior and posterior keratometry. Secondly, the use of femtosecond laser, which can cut and impact the anterior lamellar corneal fibres, to create the pocket, results in a reduction in corneal hysteresis, which is a biomechanical property of the cornea, describing its viscoelasticity and response to pressure.

In this 15 patients case series, I describe an alternative approach for treatment of advanced keratoconus with Xenia implantation, the Ghabra technique, which overcomes the limitations outlined above.

MATERIALS AND METHODS

13 patients with advanced keratoconus (grade 3–4) 2 patients (graded 2-3) who had

	PATIENT 1 PRE	PATIENT 1 POST	PATIENT 2 PRE	PATIENT 2 POST
Visual acuity	CF at 4m	6/10 UA	CF at 3m	5/10 UA
K max	68.1	49.2	75.9	48.1
Elevation front	+48	+7	+67	+2
Elevation back	+94	+26	+105	+33
High order aberrations (spherical aberrations)	-2.056	-0.096	-3.196	-0.452
Thinnest location	409	506	432	456
Topometric keratoconus staging	3-4	1-2	3-4	1-2

Table 1 - Comparison of corneal parameters, keratoconus staging, and visual acuity for 2 patient one and two before and after treatment

undergone CXL more than one year prior underwent Xenia implantation in the posterior stroma of the cornea, 100 µm from the corneal endothelium, using a manual delamination technique, sparing the lamellar corneal fibres.

Using corneal thickness readings, I calibrated a guarded knife to create a vertical incision to reach 100 µm from the corneal endothelium. In patient one, the corneal thickness was 409 µm, and so the guarded knife was calibrated to 309 microns to achieve the appropriate depth. Following this, the pocket was created to a diameter of 9 mm using a corneal dissector. The Xenia implant was introduced into the pocket using curved tying forceps. Patient two underwent a vertical incision and horizontal dissection in a similar manner.

RESULTS

A marked improvement in corneal parameters, including K max, front elevation, back elevation, high order aberrations, was observed in all patients. Correspondingly, all patients showed a decrease in their overall keratoconus staging, from severe to mild. These findings were supported objectively by an improvement in unaided visual acuity and subjectively via positive patient feedback. Please see **table 1** for the full results.

ANALYSIS

Our results show that manually creating a pocket and implanting the Xenia implant in the posterior stroma in patients who have previously undergone CXL as per the Ghabra technique results in a significant improvement in visual acuity, anterior and posterior elevation, anterior and posterior keratometry, and high order aberrations.

We believe that altering the implantation technique such that the Xenia implant is inserted in the posterior rather than anterior corneal stroma is beneficial because it serves to stiffen the posterior cornea in addition to the anterior cornea, which has already been stiffened during prior CXL procedure. The impact of CXL and Xenia implantation on the anterior and posterior cornea respectively work in combination to provide greater

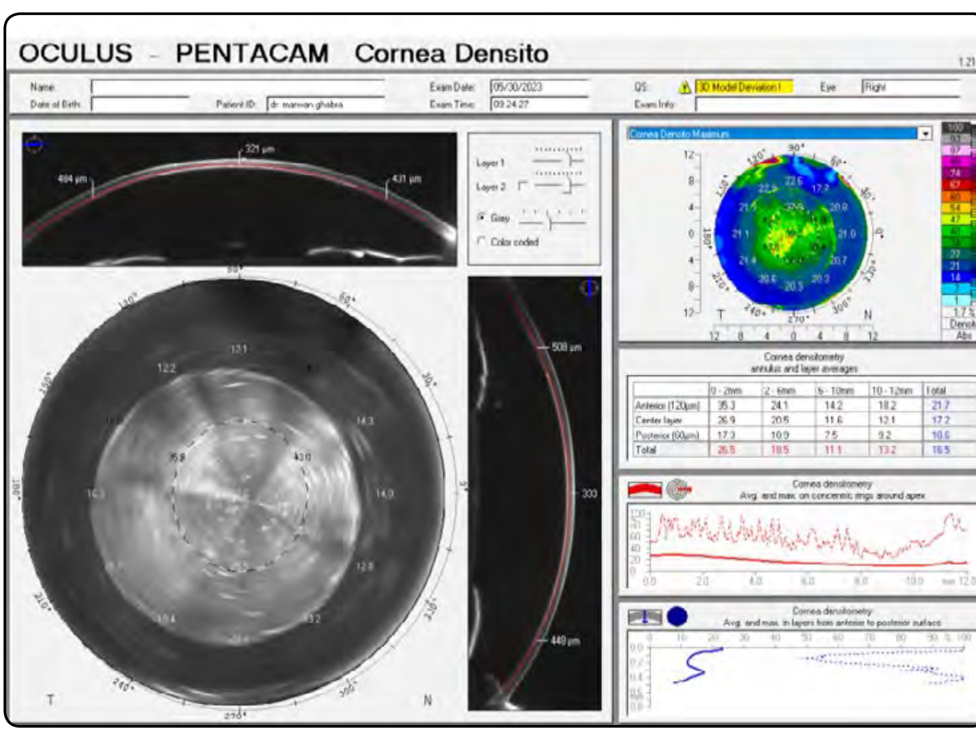

Figure 3

improvements to corneal shape and, consequently, visual acuity.

The benefits of the Xenia implant on the posterior cornea when implanted into a posterior stromal pocket also suggest that this technique could have a role to play in the treatment of early, not just advanced, keratoconus; given that early keratoconus is predominantly characterised by changes in the posterior cornea.

Though this technique could be performed using both a femtosecond laser or manual delamination to create the pocket, we believe that the latter is preferable, as it spares the lamellar corneal fibres, and thus preserves corneal hysteresis.

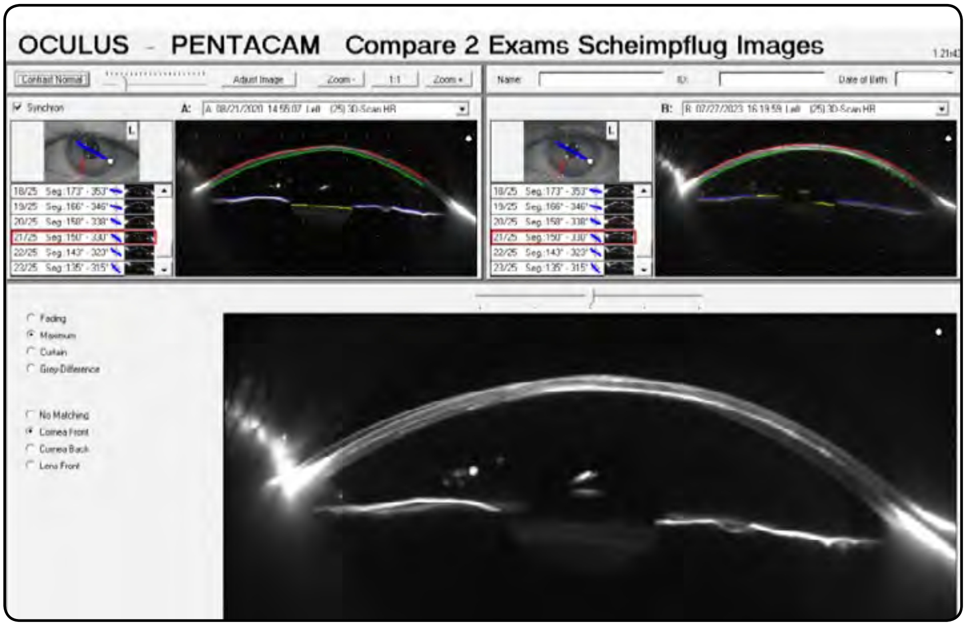

Figure 4

CONCLUSION

The Ghabra technique of posterior corneal stromal Xenia implantation with pocket creation via manual delamination in combination with anterior CXL may become the standard for comprehensive keratoconus treatment. The technique addresses both disease progression and the improvement in visual acuity.

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