

Five Years follow up of Xenia Implants for Management of Advanced Keratoconus

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DALK & PKP

Although they are the cornerstones for treatment of advanced KC , yet :

Deep *learning Curve*.

Cost and availability of the tissues.

Severe visual loss may occur due to *complications* (graft rejection, infection and suture related complications).

Long *follow up*.

Suture management and astigmatism.

Cost of drugs & *follow up visits*.



But There is an alternative

Intrastromal decellularized Porcin Corneal Lenticular Implantation



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PURPOSE

To evaluate the efficacy of implanting decellularized

Porcine lenticule (XENIA Implant) in a

femtosecond laser assisted constructed pocket for

management of advanced Keratoconus with clear

cornea.



SUBJECTS AND METHODS

Subjects and methods

- A prospective , non-randomized, non-comparative , interventional, case series on seven eyes of six patients (three eyes females and four eyes males).
- Six eyes with advanced Keratoconus, and one eye with Post-LASIK Ectasia.
- The study started in July 2019 and currently has follow up of at 60 months.



Subjects and methods

- Femtosecond assisted laser pocket creation using Visumax Zeiss Meditec Machine.
- The Porcine lenticules are produced by Gebauer Medical.
- They are decellularized and intensely cross linked.
- The lenticule is a clear 7 mm tissue with a thickness between 100 & 120 microns . (Version 1)



XENIA Implantation





First Implantation of XENIA implant. July 2019, Roayah Center ,Alexandria, Egypt.







- Lenticule is showing thin layers of tissues covering it.
- Twelve months follow up
 - Slit lamp
 - Anterior segmentOCT







Three year follow up

• Slit lamp







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Three year follow up Anterior segment OCT





Five years follow up (Slit lamp)





Five years follow up (Slit lamp)



Five years follow up Anterior segment OCT





RESULTS



The mean age of the patients was 27.67 ± 9 years.

All the surgical procedures were uneventful.

One eye had wrinkles and opacified graft, and it was exchanged 3 months postoperatively.

All patients (7 eyes) completed Five years of follow-up

No episodes of rejections were encountered up till 5 years.



Visual results

- Visual acuity improved in all patients at 6 , 12 months ,3 years and Five years
 - (Stable from 6 months till 5 years)





Central corneal thickness

- The mean CCT measured with Pentacam increased at 1,3 and 5 years.
- ?? Accuracy of Pentacam measurements.





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Corneal aberrations:



Keratometry

EDKINE CHARLES







OCULUS - PENTACAM Compare 4 Exams



OCULUS - PENTACAM Compare 4 Exams



- All cases were Cross linked three months Post corneal implant except the post lasik Ectasia.
- Epi-Off CXL.





Results (cont)

The eye of the Post-LASIK Ectasia patient reached BCVA 0.5 with -9.0 D/-2.5 x 160 glasses

5 years follow up showed stability and clear lenticules all over the follow up period.



Advantages of XENIA IMPLANTS

- > Short learning curve.
- > Ease of Implantation of grafts / availability during the pandemic.
- > Immunologically safe after Five years follow up.
- Still reversible.
- Good visual and aberrometric outcomes.
- Could save the other eye more rapidly by early implantation (No need to wait for three months for the other eye)



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- Phase 2
- Modified lenticule
- Diameter 6.75-7.2 mm
- On 220 microns depth
- > 10 eyes of Advanced keratoconus



CONCLUSIONS

Tissue augmentation with decellularized Porcine lenticules (XENIA Implants) and Corneal cross-linking results in *improvement in*

- Visual acuity.
- Corneal Curvature.
- Corneal hysteresis.
- Decreased Corneal higher order aberrations.*

* Safety and Indicative Effectiveness of Porcine Corneal Lenticular Implants in Patients with Advanced Keratoconus and Post Lasik Ectasia: A Retrospective Clinical Study. Clinical Ophthalmology. 26 July 2021. Ahmed El-Massry, Moones Abdalla, Ihab Osman, Shahira Mahmoud. <u>https://www.dovepress.com/getfile.php?fileID=72045</u>



Conclusions

- Five years follow up , confirmed the transparency, and Immunologically Stable Implants, improvement of Pentacam readings, increased thickness by U/S pachymetry.*
- Further studies with a larger number and longer follow-ups , new version of the Implants are needed to confirm its effectiveness and stability over time.

* Lenticular Intrastromal Keratoplasty for Keratoconus. Keratoconus. Chapter First Online: 28 October 2022 Mirko R. JankovII & Ahmed Elmassry <u>https://link.springer.com/chapter/10.1007/978-3-030-85361-7_86</u>



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