Research Article

Evaluation of Corneal Endothelium after Toric implantable Collamer Lens (TICL) Implantation in Keratoconus.

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Abstract
Background: the aim is to assess the effect of TICL on corneal endothelium. **Methods**: ١١ eyes of ١٥ patients with keratoconus were included in the study. Endothelial count was evaluated before TICL implantation and after ١, ٣ and ٦ months postoperative. **Results:** Preoperatively, The sphere ranges from -١٤.٧٥:-١.٢٥ with mean -٧.٠٦ ± ٣.٨٩. The cylinder ranges from -٦:-١ with mean -٣.٥١ ± ١.٦٨. The endothelial count ranges from ٢٦٥٠:٣٠١٩ with mean ٢٨٢٩.٦±١١٨.٥٨. Postoperatively, there is improvement in refraction. The sphere ranges from -٠.٧٥:٠.٢٥ with mean-٠.٢١ ± ٠.٢٩. The cylinder ranges from -١:٠.٥with mean -٠.٤١ ± ٠.٤١. The endothelial count ranges from ٢٦٥٠:٣٠١٩ with mean ٢٨٢٩.٦±١١٨.٥٨ preopratively and ranges from ٢٤٥٠:٢٨٠٠ with mean ٢٦٥١.٣٣±١٠٥.٠١ postopratively after six months. **Conclusion**: The use of TICL in keratoconic patients with myopia and myopic astigmatism is a safe and effective procedure with acceptable predictability and excellent stability up to six months.

Key words: TICL, Keratoconus and corneal endothelium.

Introduction
There are three basic factors that the health of the endothelium is classified by when evaluating the corneal endothelium. The first is the density of the endothelial cells (ie, cell density). The second is the shape of the cells (ie, polymorphism) with hexagonal cells being the most normal shape. Finally, the amount of variation in the size of the cells is also important (ie, polymegathism, or coefficient of variation). There are many factors that can influence the health of the corneal endothelium as history of contact lens use, surgical trauma, chemical or physical agents, or pH change, underlying dystrophy.[١]

Endothelium over a Lifetime [٢]

Average Cell Densities by Age[3]

Age	Average CD (cells/mm²)
10-19	2,900-3,500
20-29	2,600-3,400
30-39	2,400-3,200
40-49	2,300-3,100
50-59	2,100-2,900
60-69	2,000-2,800
70-79	1,800-2,600
80-89	1,500-2,300

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Endothelial Cell Measurement

Preoperative endothelial cell analysis is especially important in those patients with previously documented or suspe-cted abnormalities of the endothelial cells. Either slits canning corneal microscopy or specular microscopy may analyze endo-thelial cells. Generally, noncontact specular microscopy is the standard method for determining cell density, polymegathism, and pleomor-phism. There are two models of noncontact specular microscopes available: the Konan (Konan Medical Corp, Fairlawn, NJ) and the Topcon (Topcon, Paramus, NJ).[٣]

There are different computer analysis systems to be used with the microscopes. Important emphasis needs to be placed on the reliability and reproducibility of the results obtained from these systems. There can be a wide variability in the outcome variable depending upon how specific computer software is used (ie, automated, semiautomated, or manual). In addition to the wide variety of outcome dependent on software, inter technician variability is very possible.[٤]

Toric ICL

The ICL and Toric ICL are posterior chamber, sulcus located phakic intraocular lenses for the treatment of myopia, hyperopia and astigmatism. The ICL is made from hydrophilic porcine scleral tissue, a collagen-based biocompatible material known as collamer. The name comes from the combination of 'collagen' and 'polymer'. IOLs made of Collamer are highly biocompatible, and easy to implant because of the softness of the material and the gentle unfolding. Water content is very high, at about ٤٠٪, which makes this material very soft and also suitable for aphakic IOLs. The collagen in the Collamer attracts fibro-nectin, a substance found naturally in the eye. A layer of fibronectin forms around the lens, inhibiting white cell adhesion to the lens. This coating prevents the lens from being identified as a foreign object, and the lens remains unnoticed and 'quiet in the eye.[٥]

The material has a refractive index of ١.٤٥٣ at ٣٥ºC; a specific gravity of ١.٢١. The polymer material absorbs ultra-violet radiation, with light transmittance in the visible region of the spectrum of approximately ٩٠٪ ±٥٪ with over ٩٠٪ of ultraviolet radiation blocked below ٣٨٧nm wavelength. Collamer has several unique advantages. Since the collagen contained in the lens is negatively charged, it repels like charge particles such as proteins and cells. As such, the lens exhibits virtually no postoperative protein deposition.[٦]

Collamer also exhibits an inherent anti-reflective coating property. The gradual change in refractive index at the surface of the lens results in a significant reduction in glare. These properties combine to provide a lens material that induces fewer postoperative higher order aberrations than other lens materials. The ICL provides exceptional quality of vision and biocompatibility for excellent long-term stability within the eye.[٧]

Patients and methods

١٥ eyes of ١١ patients were included in the study. ٣ males and ٨ females' patients were recruited from the ophthalmology depart-ment outpatient clinic at El-Minia university hospital during the period from January ٢٠١٤ to October ٢٠١٥.

In this prospective study, the clinical outcomes of the implantable collamer lens to correct myopia and myopic astigmatism were investigated in ١٥ keratoconic eyes of ١١ consecutive patients. The patients were considered eligible to undergo implantation of the toric collamer lens if they were over ٢١ years of age, intolerant to contact lenses and spectacles, had a stable refraction for at least two years and were satisfied with their vision when wearing glasses. Patients had no other ocular and general pathology and no more than stage ٣ keratoconus according to the Amsler Krumeich classification. Inclusion criteria were anterior a chamber depth of greater than ٢.٨ mm (endothelium to anterior surface of the crystalline lens), and white to white value (W to W) of more than ١١.٠ mm. with a clear central cornea. Patients who were younger than ٢١ years, had an endothelial cell density (ECD) less than ٢,٠٠٠ cell/mm^{٢}, a history of cataract,

glaucoma, retinal detachment, macular degeneration, retinopathy, neuroophthalmic diseases or ocular inflammation were excluded from this study. The lens power calculation was performed by the manufacturer (STAAR Surgical Co.) using a modified vertex formula. The calculation is based on the following variables: manifest and cycloplegic refractions for a vertex distance of ١٢.٠ mm, keratometry and anterior chamber depth measurement. For the pIOL sizing, W to W measurement was determined using caliper. Lens power calculation for the toric collamer lens was performed using the refractive astigmatic decomposition method described by Sarver and Sanders. [٢٠] This method calculates the appropriate ICL cylinder using the patient's manifest refractive cylinder. Toric collamer lens calculation and implant-tation software allows the calculation of the spherical cylindrical power and length and also generates the toric collamer lens implantation diagram. In this study, the current V٤ ICL design was implanted. Under general anaes-thesia, dilating agents were administered. For the toric ICL implantation, the surgeon marked the zero horizontal axis during slitlamp examination while the patient was lying upright to prevent cyclotorsion. In a temporal approach, after injection of viscoelastic material, a small ٣.٢ mm clear corneal incision was made and the collamer lens was injected through this incision into the anterior chamber and allowed to slowly unfold. After injection of the toric collamer lens into the anterior chamber and its unfolding, the proper motion was performed with gentle posterior pressure and using a modified ICL manipulator. This mano-euvre was repeated for all four footplates, positioning them under the iris plane. If any adjustment of the toric collamer lens was necessary, it was accomplished with a gentle movement touching the collamer lens at the junction of the optic and haptic. Toric implantable collamer lenses are manufactured to minimise rotation and require the surgeon to rotate the lens no more than ٢٢.٥° (three quarters of a clockhour) from the horizontal meridian. All toric implantable collamer lenses have an implantation diagram to demonstrate the amount and direction of rotationfrom the horizontal axis. Irrigation and aspiration of the viscoe-lastic material were performed. An intraocular miotic (acetylcholine) was used to decrease the pupil size. Hydration of the main wound and paracentesis.

Postoperative evaluations include slit-lamp examination; IOP; visual acuity; refraction and specular microscopy.

Results

Demographic data

This study included ١٥ eyes of ١١patients, ٣ males (٢٧.٣٪) and ٨ females (٧٢.٧٪), and age ranged from ٢١ to ٣٨ years. The mean age was ٢٧.٩١ ± ٥.٣٣

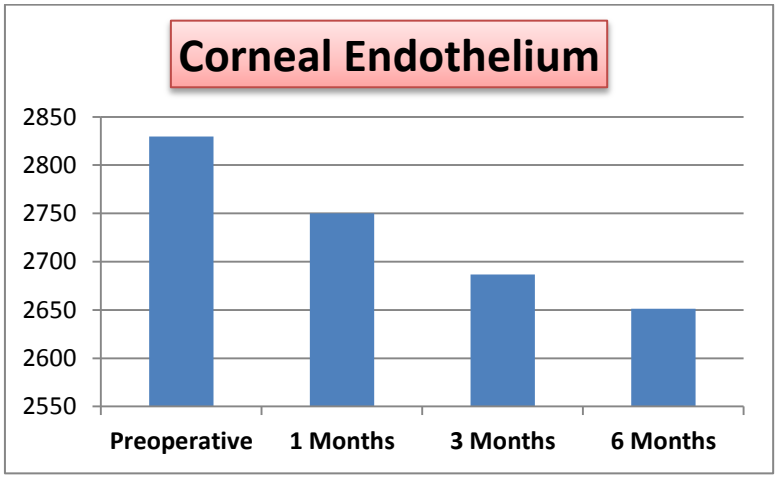
	Descriptive statistics (n=١١)
Age:	
Range	(٢١-٣٨)
Mean ± SD	٢٧.٩١ ± ٥.٣٣
Sex: n (%)	
Male	٣ (٢٧.٣٪)
Female	٨ (٧٢.٧٪)

Preoperative data
The sphere: range from -١٤.٧٥:-١.٢٥ and mean -٧.٠٦ ± ٣.٨٩.
The cylinder: range from -٦:-١ and mean -٣.٥١ ± ١.٦٨.
Endothelial count: range from ٢٦٥٠:٣٠١٩ and mean ٢٨٢٩.٦±١١٨.٥٨

	Preoperative	Postoperative		
		١ month	٣ months	٦ months
Corneal endothelium Range Mean ± SD	(٢٦٥٠:٣٠١٩) ٢٨٢٩.٦±١١٨.٥٨	(٢٦٠٠:٢٩٠٠) ٢٧٥٠±١٠٤.١٢	(٢٥٠٠:٢٨٥٠) ٢٦٨٦.٦٦±١٠٦.٩٤	(٢٤٥٠:٢٨٠٠) ٢٦٥١.٣٣±١٠٥.٠١
P value				
Preoperative		< ٠.٠٠١*	< ٠.٠٠١*	< ٠.٠٠١*
١ month			< ٠.٠٠١*	< ٠.٠٠١*
٣ months				٠.٠٠١*

Postoperative data
The Sphere: range from (-٠.٧٥:٠.٢٥) and mean -٠.٢١ ± ٠.٢٩
The cylinder: range from -١:٠.٥ and mean -٠.٤١ ± ٠.٤١

Endothelial count
After one month: range ٢٦٠٠:٢٩٠٠ and mean ٢٧٥٠±١٠٤.١٢
After three months: range٢٥٠٠:٢٨٥٠ and mean ٢٦٨٦.٦٦±١٠٦.٩٤
After six months: range ٢٤٥٠:٢٨٠٠ and mean ٢٦٥١.٣٣±١٠٥.٠١



Discussion

Refractive surgical correction of ametropia in patients with keratoconus remains challenging. Progressive thinning and subsequent anterior bulging of the cornea can lead to severe astigmatism that is often accompanied by myopia and central scarring, resulting in mild-to-marked impairment in the quantity and quality of vision.[٨]

Spectacles and contact lenses are the usual optical treatment options in the early stages of keratoconus. In more advanced cases with severe corneal astigmatism and stromal opacity, patients may not tolerate contact lenses or there may be no improvement in visual acuity on using contact lenses. In these cases, a penetrating keratoplasty (PKP) or a deep anterior

lamellar keratoplasty is necessary to restore visual function.[٩]

In this prospective study, the clinical outcomes of TICL implantation to correct myopia and myopic astigmatism were investigated in ١٥ eyes of ١١ consecutive patients with keratoconus. The safety, predictability, stability and efficacy of this method were also determined. At present, toric implant-table collamer lenses are available with spherical powers from -٣.٠٠ to -٢٣.٠٠ D for correction of myopia and a refr-active astigmatic power up to ٦.٠٠ D.

The endothelial cell count evaluated after ١, ٣ and ٦ months. We noticed cell loss associated with TICL.

There are similar reports of documented cell loss associated with implantation of a posterior chamber phakic IOL in addition to reported cell loss associated with implant of an anterior chamber phakic IOL. In a study conducted by Jimenez-Alfaro et al., ٢٠ eyes under-went implantation of the STAAR posterior chamber phakic IOL (PCPIOL) (STAAR Surgical AG, Nidau, Switzerland). Several factors were evaluated to determine the safety of the procedure. The authors found that central endothelial cell density decreased significantly after the surgery. Cell loss was ٤.٤٪ at ٣ months, ٤.٨٪ at ٦ months.[١٠]

Dejaco-Ruhswurm et al conducted a similar study evaluating long-term changes to the corneal endothelium with a STAAR PCPIOL with similar findings. Cell loss was ١.٨% at ٣ months, ٤.٢٪ at ٦ months, ٥.٥٪ at ١٢ months. This study also evaluated morphometric changes, including polymerphism (hexagonal cells) and polymergathism (coefficient of varia-tion), both of which remained stable over the entire follow up period.[١١]

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