• Clinical Research •

Two-stage procedure in the management of selected cases of keratoconus: clear lens extraction with aspherical IOL implantation followed by WFG-PRK

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Received: 2018-05-21 Accepted: 2018-07-18

Abstract

• AIM: To assess the objective and subjective results of a two-stage procedure for management of keratoconus: clear lensectomy with aspherical intraocular lens (IOL) implantation followed by wave front-guided photorefractive keratotomy (WFG-PRK).

• METHODS: This prospective interventional non-randomized study included patients aged 35 years old or more with grade I and II stable keratoconus, a clear visual axis, minimal corneal thickness (MCT) 420 μm or more and average keratometric reading (K) less than 54 diopter (D). Refraction of all selected eyes should be -8.00 D sphere or more with less than -6.00 D cylinder and could be corrected two lines or more with spectacles or contact lenses. All studied eyes underwent a two-stage approach treatment: first refractive lens exchange and aspherical IOL implantation followed, after at least 3mo, by WFG-PRK. Pre and postoperative complete ophthalmological examination were performed. Topographical, visual and aberrometric results were recorded and evaluated during 6mo follow up period. Moreover, patient satisfaction and other subjective outcomes were also analyzed.

• RESULTS: The 13 eyes of 11 patients diagnosed with stable keratoconus and aged from 39 to 49y (42.4±6.2y) were enrolled in the study. At baseline, 8 eyes had grade I and 5 eyes had grade II keratoconus. The manifest sphere was -10.3±4.2 D (ranged from -8.0 to -14.0 D) and the manifest cylinder was -4.2±1.2 D (ranged from -1.75 to -5.50 D). After the two-stage procedure, sphere and cylinder reduced significantly to -0.43±0.22 D and -1.3±0.72 D respectively (*P*<0.001). There was also a highly significant improvement in the mean uncorrected distance visual acuity (UDVA) from logMAR 1.41±0.49 preoperatively to 0.51±0.16 postoperatively (*P*<0.001) and the mean corrected distance visual acuity (CDVA) from 0.76±0.24 preoperatively to 0.49±0.13 after the operation (*P*<0.001). All aberrometric and mesopic vision parameters and most of the topographical indices demonstrated highly significant improvement that remains stable until the end of follow up. All recorded subjective data revealed a high degree of patient satisfaction.

• CONCLUSION: Two-stage approach (clear lens exchange with monofocal IOL followed by WFG-PRK) in selected cases of keratoconus is a safe, effective and highly predictable procedure with satisfactory visual and refractive results.

• KEYWORDS: keratoconus; clear lensectomy; wave front-guided photorefractive keratotomy

DOI:10.18240/ijo.2018.11.05

Citation: Abou Samra W, Mokbel T, Elwan M, Saleh S, Elwehidy A, Iqbal M, Ellayeh A. Two-stage procedure in the management of selected cases of keratoconus: clear lens extraction with aspherical IOL implantation followed by WFG-PRK. *Int J Ophthalmol* 2018; 11(11):1761-1767

INTRODUCTION

Keratoconus is a primary corneal ectasia characterized by a corneal thinning, progressive steepening, and conical shape of the cornea, that results in marked degree of irregular corneal astigmatism and subsequent visual deterioration[1]. Although the disease might progress as late as 70y, in most of cases progression usually stops at the third decade in life[2].

Corneal collagen cross-linking (CXL) is the only established management which is approved to hinder or at least to slow keratoconus progression[3-5]. Moreover, visual improvement could be achieved by different interventions such as spectacles, contact lenses[6-7], intra corneal rings (INTACs)[8-9], photorefractive keratotomy (PRK)[10-11] and intraocular lenses (IOLs; phakic

and pseudophakic)[12-14]. However, keratoconus can be present in eyes with high degree of myopia and with a significant degree of corneal astigmatism.

Previous investigations and studies focused on visual outcomes and the IOL power calculation in patients with non-progressive keratoconus and cataract[13,15-17]. We previously recorded the results of clear lensectomy with toric IOL implantation after CXL in selected cases of progressive keratoconus[12]. In this study, we aimed to evaluate the safety and efficacy of a two-stage procedure comprising clear lens extraction followed by wave front-guided photo refractive keratotomy (WFG-PRK) to improve vision in patients above 35y with non-progressive keratoconus, high myopia, and mild to moderate amount of corneal astigmatism.

SUBJECTS AND METHODS

In this prospective interventional non-randomized study, patients aged 35 years old or more (42.4±6.2y) with grade I and II stable keratoconus (according to pentacam indices)[18] were selected from Outpatient Clinics of Mansoura Ophthalmic Center, Mansoura University. Keratoconus was diagnosed according to slit-lamp examination and Scheimpflug corneal topography (Pentacam; Oculus Optikgeraete GmbH, Wetzlar, Germany)[19]. Cases of keratoconus with a clear visual axis, minimal corneal thickness (MCT) 420 μm or more and average keratometric reading (K) less than 54 diopter (D) were included in the study. Keratoconus was documented to be a stable at least for one year before the study.

Exclusion criteria included progressive cases in which corneal topography revealed change in the maximum keratometry (Kmax) more than 1.00 D, decrease in the MCT 20 μm or more or increase in the cylinder more than 0.50 D during the 1-year follow-up. Other excluded cases were cases of dry eye syndrome, apical scarring, endothelial cell count less than 1500, corneal pachymetry less than 420 μm fundus disorders, glaucoma and pregnancy or lactation during the course of the study. Patients with a history of ocular inflammation or surgery and any other ocular or systemic disease that might affect epithelial healing were also excluded from the study.

Refraction of all studied eyes should -8.00 D sphere or more with less than -6.00 D in the cylinder and could be corrected with spectacles or contact lenses two lines or more. The mean refractive sphere of studied eyes was -10.3±4.2 D (range -8.0 to -14.0 D). The mean refractive cylinder was -4.2±1.2 D (range -1.75 to -5.50 D).

In instances of lenses usage, patients were instructed to stop utilization of their lenses no less than a month prior to the study for precise measurements.

The expected residual corneal stromal bed thickness in the 2nd stage should not be lower than 350 μm (excluding the epithelium thickness) after ablation of 50 μm maximally. Nonetheless, we attempted correction of 80% of the measured cylinder if the estimated ablation surpassed 50 μm.

The study was agreed by the Institutional Review Board of the Mansoura Faculty of Medicine. It followed the tenets of the Declaration of Helsinki. All patients signed a written informed consent after explanations of risks and profits of the procedure.

Ophthalmological examination of the studied patients included uncorrected and corrected distance visual acuity (UDVA, CDVA), patient's refraction, anterior segment examination, fundoscopy and tonometry (IcareONE, Finland Oy, Espoo, Finland). Topographical corneal parameters were recorded using Pentacam-HR system (Oculus Optikgeraete GmbH, Wetzlar, Germany). They included flattest and steepest keratometric readings (K1 and K2), Kmax, MCT, corneal asphericity (Q value) and different corneal regularity indices such as index of surface variation (ISV), index of height asymmetry (IHA), index of vertical asymmetry (IVA), minimum radius of curvature (Rmin) and keratoconus index (KI).

Using a high-resolution aberrometer, (Zywave II, Bausch and Lomb, Munich, Germany), the total root mean square (RMS) and higher order aberration (HOA) RMS were estimated in the studied eyes.

Contrast and Glare Sensitivity Test The test was done using Mesotest II (Oculus, Germany) for measurement of mesopic vision, which comprises different contrast levels of Landolt rings presented in front of a low-brightness background. According to the ration between optotypes light intensity and the background, there are 4 different levels of contrast: 1:2/1:2.7/1:5/1:23. So that, we have 8 tests, 4 without and 4 with glare. Test 1, with contrast level 1:23, is the most easily recognizable one and is given the least score (25%). On the other hand the most difficult test (with 1:2 contrast level) is given a 100% score.

Surgical Technique In the first stage, IOL power was calculated using the Zeiss IOL Master. SRK-II formula was used with a target of low myopia. A standard phacoemulsification was performed with the same experienced surgeon (Abou Samra W). Aspheric monofocal Tecnis posterior chamber intraocular lens (PCIOL; Abbot Medical Optics, Bloomington, MN, USA) was implanted in all operated eyes. Moxifloxacin eye drops (Vigamox, Alcon Laboratories) were used post operatively for one week and prednisolone acetate eye drops (Econopred, Alcon Laboratories) were prescribed for 3wk in a decreasing fashion. The patients were followed for 3mo with evaluation of the visual acuity (VA), intraocular pressure, manifest refraction and the anterior segment integrity.

The 2nd stage of visual rehabilitation was done 3mo after phacoemulsification. The refraction was refined in 3 repeated visits using retinscopy and cyclopelagia at least in one visit to clear the effect of ciliary muscles spasm.

Under topical anesthesia, the epithelium was removed manually in a centripetal fashion using a blunt hockey blade. WFG-PRK ablation was then performed using TENEO 317 Excimer LASER (TECHNOLAS Perfect Vision GmbH-A Bausch & Lomb Company, Munich, Germany) according to the measurements obtained with the ocular Zywave II aberrometer. An adjustment to the LASER profile was applied to ensure minimal tissue removal (not to exceed 50 μm) by reducing the sphere component with or without changing the cylinder and/or reducing the effective optical zone diameter. Mitomycin C 0.025% solution was applied for 20s over the ablated tissue followed by irrigation with cold balanced salt solution.

All operated eyes were treated postoperatively with topical gatifloxacin 0.3% (Zymer, Allergan Laboratories) applied 3 times daily up to 1wk. A combination of tobramycin with dexamethasone (Tobradex; Alcon Laboratories) was prescribed 4 times daily for 4wk with gradual withdrawal. The patients were instructed to use tear substitute every 2h for one month or more (Systane Ultra, Alcon Laboratories). A bandage soft contact lens (Biomedics, Cooper Vision, Scottsville, NY, USA) was applied.

Assessment of epithelial healing was done during the 1st week after the PRK. Accordingly, the therapeutic contact lens was removed or replaced till complete epithelialization was noticed. The studied patients were examined 3 and 6mo after the 2nd stage surgery with assessment of VA and manifest refraction. Corn wave front aberrometry, mesopic vision, were also performed in each visit.

Subjective Analysis Assessment of subjective data in this research was carried out by requesting the patients to fill a survey just before the execution of refractive lens exchange and 6mo after the full procedure. It comprised visual clarity, patient satisfaction, limitations of daily activities, spectacle dependence and other visual disturbance items (such as glare, halo, and diplopia).

Visual clarity, patient satisfaction was scored on a scale of 1 (none) through 5 (excellent) while visual symptoms were scored on a scale of 1 (none) through 5 (severe). The subjective outcome data were recorded as the mean of the score given by the studied patients for each asked parameter.

Statistical Analysis Statistical package SPSS version 16 for Windows (SPSS, Inc., Chicago, IL, USA) was used to analyze the collected data. The presented values are the means and SD for each study variable. VA measurements were calculated as logMAR. The one-way repeated measure of analysis of variance (RM-ANOVA) was applied to assess the trend of the different parameters assessed in this study. The Wilcoxon Rank Sum test for paired data was used to assess the significance of differences between preoperative and postoperative data at each visit. The level of significance was always the same (P<0.05).

Table 1 Demographic data of studied patients

Parameters	Values
No. of patients (eyes)	11 (13)
Sex (M:F)	5:6
Mean age±SD (y)	42.4±6.2
Age range (y)	39-49
Mean refractive sphere±SD (D)	-10.3±4.2
Range of refractive sphere (D)	-8.0 to -14.0
Mean refractive cylinder±SD (D)	-4.2±1.2
Range of refractive cylinder (D)	-1.75 to -5.50
MRSE (D)	-12.4±4.8
Kmax (D)	49.3±4.5
Thinnest pachymetry (μm)	472±35

MRSE: Mean refractive spherical equivalent; Kmax: Maximum keratometry.

Table 2 Visual and refractive parameters of the studied patients preoperatively and 3mo after phacoemulsification mean±SD

Parameters	Preop.	Postop.	P^a
UDVA	1.41±0.49	0.73±0.37	<0.001
CDVA	0.76±0.24	0.52±0.18	0.002
Sphere (D)	-10.3±4.2	-0.76±0.32	<0.001
Cylinder (D)	-4.2±1.2D	-4.00±1.1	0.07
MRSE (D)	-12.4±4.8	-2.8 ±1.5	<0.001

[a]Wilcoxon signed-rank test. UDVA: Uncorrected distant visual acuity; CDVA: Corrected distant visual acuity; MRSE: Mean refractive spherical equivalent.

RESULTS

The 13 eyes of 11 patients (5 males and 6 females) were enrolled in the study. They aged 42.4±6.2y (range 39-49y). According to pentacam indices, 8 eyes had grade I and 5 eyes had grade II keratoconus. Table 1 summarized the preoperative data of the studied patients.

Visual and Refractive Outcomes Pre and postoperative data after 1st stage surgery (phacoemulsification with an aspherical IOL implantation) were recorded in Table 2. While the studied visual and refractive parameters after the first stage and 3 and 6mo following the full procedure were demonstrated with corresponding P values in Table 3.

Corneal Topographical Changes Corneal morphological changes measured by pentacam were recorded in Table 4 that summarizes the preoperative baseline parameters and the postoperative values 3 and 6mo after the full procedure.

Ocular Aberrometric and Mesopic Vision Changes Ocular aberrometric parameters including the total RMS and HOA RMS and mesopic vision parameters including values of contrast sensitivity and glare tests were demonstrated in Table 5.

Subjective Data Subjective data and different measures of patient satisfaction were recorded in Table 6.

Table 3 Visual and refractive parameters of the studied patients preoperatively and 3 and 6mo following the full procedure mean±SD

Measure	Preop. measure	P^a; preop. *vs* 3mo after PRK	3mo after PRK	P^a; preop. *vs* 6mo after PRK	6mo after PRK	*P*; repeated measures ANOVA
UDVA (logMAR)	0.73±0.37	<0.001	0.50±0.17	<0.001	0.51±0.16	<0.001
CDVA (logMAR)	0.52±0.18	0.03	0.50±0.13	0.02	0.49±0.13	<0.01
Refractive sphere (D)	-0.76±0.32	<0.001	-0.41±0.19	<0.001	-0.43±0.22	<0.001
Refractive cylinder (D)	-4.00±1.1	<0.001	-1.5±0.70	<0.001	-1.3±0.72	<0.001
MRSE (D)	-2.8 ±1.5	<0.001	-1.00±0.57	<0.001	-1.1±0.59	<0.001

[a]Paired *t*-test (Wilcoxon signed-rank test). UDVA: Uncorrected distant visual acuity; CDVA: Corrected distant visual acuity; MRSE: Mean refractive spherical equivalent.

Table 4 Topographical parameters of the studied patients preoperatively and 3 and 6mo following the full procedure mean±SD

Measure	Preop. measure	P^a; preop. *vs* 3mo after PRK	3mo after PRK	P^a; preop. *vs* 6mo after PRK	6mo after PRK	*P*; repeated measure ANOVA
K1 (D)	44.3±1.72	0.003	43.1±1.31	0.002	43.1±1.30	<0.001
K2 (D)	48.9±2.34	<0.001	44.2±1.22	<0.001	44.1±1.26	<0.001
Kmax (D)	49.3±3.9	<0.001	45.4±4.6	<0.001	45.2±4.3	<0.001
Q	-0.71±0.33	<0.001	-0.28±0.21	<0.001	-0.28±0.23	<0.001
MCT	472±35	<0.001	419±22	<0.001	421±28	<0.001
ISV	45.7±23.8	<0.001	39.6±22.9	<0.001	39.2±23.1	<0.001
IVA	0.46±0.31	0.09	0.45±0.28	0.08	0.45±0.29	0.06
IHA	21.7±10.6	0.68	21.5±10.8	0.70	21.2±11.1	0.77
Rmin	6.8±0.55	<0.001	7.3±0.49	<0.001	7.4±0.43	<0.001
KI	1.3±0.09	0.002	1.05±0.1	0.001	1.074±0.1	<0.001

[a]Paired *t*-test (Wilcoxon signed-rank test); Kmax: Maximum keratometry; Q: Corneal asphericity; MCT: Minimum corneal thickness; ISV: Index of surface variance; IVA: Index of vertical asymmetry; IHA: Index of height asymmetry; Rmin: Minimum radius of curvature; KI: Keratoconus index.

Table 5 Aberrometric and mesopic vision parameters of the studied patients preoperatively and 3 and 6mo after the full procedure mean±SD

Measure	Preop. measure	P^a; preop. *vs* 3mo after PRK	3mo after PRK	P^a; preop. *vs* 6mo after PRK	6mo after PRK	*P*; repeated measure ANOVA
Total RMS	6.2±1.59	<0.001	2.3±0.81	<0.001	2.1±0.77	<0.001
HOA RMS	1.4±0.78	<0.001	0.67±0.34	<0.001	0.65±0.31	<0.001
Coma RMS	0.62±0.22	<0.001	0.36±0.11	<0.001	0.35±0.12	<0.001
Trefoil RMS	0.34±0.15	<0.001	0.22±0.10	<0.001	0.22±11	<0.001
Contrast sensitivity (%)	34.2±9.9	<0.001	72.1±11.3	<0.001	73.1±13.1	<0.001
Glare (%)	26.1±10.3	<0.001	49.7±10.2	<0.001	50.1±10.8	<0.001

[a]Paired *t*-test (Wilcoxon signed-rank test); RMS: Root mean square; HOA: High order aberration.

DISCUSSION

Nowadays, many options for visual rehabilitation are available for keratoconic patients including intracorneal ring segment (ICRS) implantation[20-21], phakic intraocular lenses (PIOL)[14], PCIOL[16] and PRK[10,22-23]. Lens exchange with PCIOL is used in patients with moderate to severe ametropia with good BCVA while PRK is used to correct mild refraction error and corneal irregularities thus reducing HOAs. Although PIOL may be a good choice, it is considered as an expensive temporary solution of the refractive problem compared with pseudophakic IOL implantation that can manage the problem during lifetime especially if we know that patients older than 35y start to lose their accommodation. Our study group recently published the data on the safety and efficacy of clear lens extraction with toric IOL implantation after corneal CXL for correction of myopia and astigmatism in patients with keratoconus[12].

Table 6 Preoperative and postoperative patient self-assessed subjective ratings of various parameters mean±SD

Parameters	Preop.	Postop.	P^a
Clarity of vision	2.61±0.51	3.9±0.58	0.001
Patient satisfaction	1.64±0.42	4.37±0.41	<0.001
Visual fluctuation	3.33±0.41	1.77±0.37	<0.001
Glare	2.67±0.47	1.93±0.65	0.007
Halo	2.67±0.47	1.83±0.48	0.003
Starburst	3.00±0.58	1.11±0.63	0.005
Diplopia	0.91±0.19	0.33 ±0.17	0.004
Activity limitations	3.17±0.37	0.88±0.42	<0.001
Far spectacle dependence	5.00±0.00	0.33±0.29	<0.001
Near spectacle dependence	3.13±1.99	2.17±1.79	0.007

[a]Wilcoxon signed-rank test.

However, there are still many debates about the use of toric IOL, which may fail to neutralize the irregular portion of corneal astigmatism in keratoconus and affect the final visual results. Second, it is very difficult to determine the exact axis and the power of the implanted lens, which lead to unpredictable results in many cases. Moreover, it may be required to exchange the toric IOL with an aspherical IOL design due to the manifest astigmatism of the lens if a corneal transplant surgery is done or if the patients want to wear a rigid gas permeable (RGP) lens[24].

To the best of our knowledge the current research is the first report about the results of clear lensectomy with aspheric IOL followed by WFG-PRK in keratoconic eyes with moderate to severe myopia and astigmatism.

Compared to the traditional spherical IOLs that do not address spherical aberration, Tecnis PCIOL (Abbot Medical Optics, Bloomington, MN, USA) incorporates a modified anterior prolate surface that reduces the spherical aberration and improves patients' quality of vision as well as their Snellen VA. Moreover, it is characterized by an offset haptic design that vaults the optic posteriorly. This provides constant capsular contact, which not only reduces lens epithelial cell migration and posterior capsular opacity but also helps to rapidly stabilize IOL position and refraction.

Difficulties in IOL power calculation in keratoconus make the lens exchange in such cases very challenging[15,25-26]. Unfortunately, a postoperative hyperopic shift is expected in theses cases due to overestimation of the corneal power and subsequent IOL power underestimation. That is why we indented the target of a low degree of myopia that results in an acceptable postoperative outcome (Table 2).

IOL power was achieved with the SRK-II formula, according to Thebpatiphat *et al*[17] who found that this formula is the most accurate one in keratoconic patients.

Although many researches studied the topography-guided PRK (TG PRK) in management of keratoconus[27-32], very few reports recorded the data using WFG-PRK in such patients[10,33]. WFG-PRK was done in the studied eyes using Zywave II aberrometer device, which has a high capability of ocular aberrations measurement. Such PRK can regularize, to some extent, the corneal surface due to flattening of the cone. Refractive and topographical stability of treated eyes with PRK was recorded by many authors for several years[34-36]. This makes WFG-PRK treatment not only a refractive procedure but also a therapeutic one.

Visual and Refractive Outcomes The recorded data revealed highly significant improvement in all measured visual and refractive parameters after the full procedure. No significant changes were demonstrated till the end of follow up (Table 3). Shaheen *et al*[33] found similar results using sequential WFG-PRK one year after CXL in keratoconus. On the other hand, using non-topography-guided PRK with CXL in early cases of keratoconus, Fadlallah *et al*[11] noted significant improvement in the cylinder, spherical equivalent and UDVA, while the CDVA did not change significantly. Spherocylindrical error reduction and HOAs minimization were the reasons of the visual improvement in both UDVA and CDVA recorded in our study. The mean refractive spherical equivalent (MRSE) was reduced from a mean preoperative value of -12.4±4.8 D to a postoperative value of -1.10±0.59 D.

Our data showed a significant reduction in the manifest cylinder from a preoperative value of -4.2±1.2D to a 6-month postoperative value of -1.3±0.72. Similar results were reported by Sakla *et al*[37] who revealed a significant reduction of refractive astigmatism from -2.77±1.47 D to -0.98±0.76 D. The results of our study supported the theory demonstrated by Nagpal *et al*[38] who studied the outcome of monofocal IOL and PRK versus toric IOL implantation and terminated that PRK is more accurate in astigmatism correction after cataract surgery as the refractive outcome following PRK depends on precise preoperative measurement. Moreover, the excimer procedures are more predictable in the correction of mild refractive errors.

However, the astigmatic under-correction observed in our results might be due to the difficulty in obtaining an accurate preoperative measurement of refractive cylinder in keratoconic eyes. Furthermore, the effect of epithelial remodeling and the response of such cornea, with altered biomechanical hysteresis, to the laser ablation may be also other contributing factors to the demonstrated under-correction. As in our previous studies in keratoconus, we repeated patient's refraction with retinoscopy and trial lenses at least three times with at least one cycloplegic refraction to relieve the accommodation spasm that can affect the final refractive outcome of such patients[10]. Therefore, the observed refractive under-correction after the full procedure is much lower than recorded with other refractive lines for keratoconus, such as ICRS[39].

Corneal Topographic Changes Our results demonstrated a significant postoperative improvement in the corneal topographic parameters with decreased K1, K2, Kmax, Q, ISV and KI and increased Rmin (Table 4). Similarly, another study carried out by Shaheen *et al*[33] revealed a significant reduction in the keratometric readings, Q value, ISV and KI with improvement in other corneal indices.

Previous studies demonstrated that PRK surface ablation can maintain the hysteresis and mechanical properties of the cornea in a better way than other refractive surgical techniques[40-41]. The ablated corneal layers may be replaced by a new fibrocellular membrane that subsequently increases the corneal rigidity and hinder further keratoconus progression[42].

Ocular Aberrometric and Mesopic Vision Changes Our data revealed a significant reduction of the total RMS, HOA, coma and trefoils values after the full procedure (P<0.001). These results go hand in hand with that recorded in our previously published research about simultaneous versus sequential accelerated CXL and WFG-PRK for treatment of keratoconus[10]. Similarly, Shaheen *et al*[33] noted significant reduction in aberrometric parameters after sequential WFG-PRK and CXL.

The recorded values of contrast sensitivity and glare tests revealed significant postoperative improvements (P<0.001). Such results go hand in hand with the noted data in our previous work of WFG-PRK and CXL in keratoconic patients[10]. The remarkable improvement in aberrometric and mesopic vision (Table 5) and subsequently the CDVA is attributed to the reduction of corneal surface irregularity that is the main reason of aberrations in keratoconic eyes.

Subjective Data As far as we know this is the first report that demonstrates the subjective data of clear lensectomy with aspheric IOL implantation followed by WFG-PRK in keratoconic eyes.

All measured parameters showed statistically significant improvement with high level of patient satisfaction after the surgical approach (Table 6).

In conclusion, this two-stage procedure in non-progressive cases of keratoconus with high myopia and mild to moderate astigmatism is a safe, effective and highly predictable approach that provides the patients with satisfactory visual and refractive outcome. However, larger sample size with longer follow up period are recommended in future studies to confirm the stability of the results.

ACKNOWLEDGEMENTS

Conflicts of Interest: Abou Samra W, None; **Mokbel T,** None; **Elwan M,** None; **Saleh S,** None; **Elwehidy A,** None; **Iqbal M,** None; **Ellayeh A,** None.

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