Surgical management of coexisting corneal and lens opacities: one-stage vs two-stage approach
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Introduction
Many patients especially elderly people with corneal diseases necessitating PKP also require cataract surgery. However, there is controversy, with some surgeons preferring the triple procedure (combined PKP and cataract extraction and IOL implantation) [1–3], whereas others favoring sequential surgery (PKP followed by cataract surgery later on) [4,5].

The triple procedure became popular because it offers the potential of more rapid visual rehabilitation. Moreover, one procedure can preserve the graft endothelial cells during cataract extraction [6]. However, difficulties in predicting postkeratoplasty corneal power have become apparent especially in case of corneal diseases that affect the corneal refractive power, such as keratoglobus or keratoconus. In other patients, it is impossible to obtain measurable and reliable keratometry values, and therefore, it is necessary to apply standard biometric values [7].

On the contrary, sequential surgery may result in a better refractive outcome. In addition, sequential surgery has an opportunity to correct postkeratoplasty astigmatism by performing arcuate keratotomies or using a toric IOL. To achieve this goal, cataract extraction should be delayed for at least 6 months after penetrating keratoplasty procedure. During this period, sutures can be removed, and graft curvature is stabilized [1]. However, two-stage surgeries have the disadvantages of late visual rehabilitation, the cost and risks of a second

Purpose
The aim was to compare the refractive and visual outcome of the triple procedure and the sequential surgery and to report any adverse effects or complications of each approach.

Patients and methods
Forty eyes of 40 patients with corneal opacity and visually significant cataract were divided into two equal groups: the triple group (group I) and the sequential group (group II). In group I, patients underwent PKP with cataract extraction by either open sky ECCE technique or phacoemulsification according to the degree of corneal clarity. In group II, patients first underwent PKP then scheduled for phacoemulsification and intracocular lens implantation. All patients were followed up for 1 year, and data including the visual acuity, refractive outcome, ECC and complications were recorded and analyzed.

Pkp penetrating keratoplasty ECCE extracapsular cataract extraction

Results
After 1 year of follow-up, the mean best corrected visual acuity (BSCVA) was 0.35 ±0.13, with 45% of eyes with BSCVA greater than or equal to 0.5 in group I. In group II, the mean BSCVA was 0.52±0.12 (P=0.021), with 60% of eyes with BSCVA greater than or equal to 0.5(P=0.14). Mean spherical equivalent after triple procedure was −1.6±0.2 D. Mean spherical equivalent following sequential surgery was −0.29±0.24 D (P=0.00). The mean cylinder after combined surgery was −3.85±1.21, compared with −3.45±0.82 D after sequential surgery (P=0.231). Overall, 50% of group I and 70.0% of group II patients were within ±2 D of the target refraction (P=0.19). No significant difference in the mean ECC was found at the end of follow-up period (P=0.524).

Conclusion
Planned phacoemulsification after PKP is a safe and effective approach for management of coexisting lens and corneal opacity.
anaesthesia, and decrease in the endothelial cell count in the donor graft [6].

Patients and methods
Eyes with corneal pathology necessitating PKP and had co-existing visually significant cataract were included in this study. During the study period from July 2016 to June 2019, 40 eyes of 40 patients were included in the study as a comprehensive sample. They were divided into two equal groups: the combined group (group I) and the sequential group (group II). Patients with retinal disorders, patients with uncontrolled glaucoma, patients with active or previous uveitis, patients with stem cell deficiency, and patients with active keratitis or corneal melting were excluded. The protocol was reviewed and approved by the Ethics Committee of Zagazig University Hospital before initiating this study (IRB #: 2809/6-4-2016).

All patients were subjected to preoperative assessment with complete medical and ophthalmic examination, including uncorrected visual acuity (UCVA), refraction (whenever possible), best spectacle-corrected visual acuity (BCVA) presented by the decimal notation, slit-lamp examination, retinal evaluation and tonometry using applanation tonometry, corneal topography using Sirius 3D Rotating Scheimpflug Camera and Topography System with software suite Phoenix v2.1 (Costruzione Strumenti Oftalmici, Florence, Italy), and biometry using either A-scan ultrasonography (Digital A/B scan 5500; Sonomed Inc., Lake Success, New York, USA) or IOLMaster 500 (Carl Zeiss Meditec AG, Jena, Germany). IOL power calculation was done by SRK/T formula using a standard constant keratometry value of 44 D in the triple group, and the actual keratometric values from the corneal topography of the transplanted cornea in the sequential group (emmetropia was targeted in all eyes). Corneal endothelial cell count was estimated by specular microscope CEM-530 (Nidek Co. Ltd, Gamagori, Japan). The degree of cataract was categorized based on the LOCS III [8].

The triple procedure
Under general anaesthesia and after pupillary dilation, PKP procedure was performed using the standard technique. A Barron suction trephine (CORONET; Network Medical Products, North Yorkshire, UK) was centered over the central corneal mark and suction applied. After the trephine was removed, the wound was inspected, and the AC entered with a sharp blade. The AC was reinflated with viscoelastic material to maintain the integrity of the eyeball, and the corneal scissors were used to remove the recipient cornea. The donor cornea was punched out from the endothelial side with diameters ranging from 7.25 to 8 mm using the Barron donor punch (CORONET; Network Medical Products). Donor recipient disparity was 0.25 mm in keratoconic eyes and 0.5 mm in other conditions. Cataract extraction was done by either open sky ECCE or phacoemulsification according to the degree of corneal clarity. The suturing technique consisted of 16 bite interrupted 10-0 nylon suture.

The sequential surgery
Patients in this group first underwent PKP as described, except that topical mydriatic was not used to dilate the pupil. Phacoemulsification and IOL implantation was scheduled for at least 6 months after PKP. Phacoemulsification was performed under peribulbar anesthesia. Main incision was made outside the graft. The anterior chamber was filled with OVD, and CCC was performed with a capsulorhexis forceps. After hydrodissection, phacoemulsification was performed by the stop and chop technique. Then a foldable acrylic hydrophilic IOL was inserted within the capsular bag.

Postoperative follow up
All eyes received antibiotic and steroid eye drops and other topical medications (such as for glaucoma) as appropriate. All patients were scheduled for follow-up and postoperative evaluation at 1 day, 3 days, 1 week, 1 month, and 3 months postoperatively and then every 3 months for 1 year. On each visit, BCVA, autorefractometer readings whenever possible, slit lamp examination, and tonometry were performed.

If astigmatism was more than 4 Diopter during the follow-up, it was treated in the third month postoperatively by selective suture removal guided by the corneal topography.

Statistical analysis
Data were statistically analyzed using the Statistical Package for the Social Sciences (SPSS version 20.0) software. \( \chi^2 \)-Test was used to test differences for significance of qualitative variable. Differences between quantitative independent groups were tested by \( t \)-test or Mann–Whitney \( U \)-test, and paired by paired \( t \) or sign. \( P \) value was set at less than 0.05 for significant results and less than 0.001 for highly significant result.
Results

In group I, nine (45%) males and 11 (55%) females were included, and for group II, eight males and 12 females were included in a percent of 40 and 60%, respectively ($P=0.74$). The mean age for group I was 55.4±14.38 years (range: 21–75 years), whereas the mean age for group II was 54.35±13.66 years (range: 21–67 years) ($P=0.814$) (Table 1).

There were 12 (60%) eyes with corneal scars in group I, whereas in groups II, there were 12 (60%) eyes with corneal scars ($P=0.61$). Five (25%) eyes were diagnosed clinically to have corneal dystrophy in group I. Moreover, there were six (30%) eyes with corneal dystrophy in group II ($P=0.53$). Advanced keratoconus was present in three (15%) eyes in group I and two (10%) eyes in group II ($P=0.42$).

In group I, open sky ECCE was performed in 18 (90%) eyes, whereas phacoemulsification followed by PKP was done in two (10%) eyes: one eye was diagnosed with keratoconus, and the other one had corneal scar from previous trauma.

In the ECCE subgroup, after successful trephination, trypan blue was used to stain the capsule in all cases expect one eye which had a very good red reflex. Narrow pupil owing to previous synechia especially in cases with previous infectious keratitis was released mechanically. Extended capsulorhexis was encountered in two (10%) eyes, which were completed with scissors followed by successful nucleus delivery in all cases. Delivery was performed by irrigation in 16 (70%) eyes and phacoprobe-assisted delivery in two (10%) cases. No vitreous loss was encountered in any case, and rigid IOL was implanted in all cases. In phacoemulsification subgroup, foldable IOL was implanted in the bag without vitreous loss or capsular rupture.

Small incision phacosurgery was performed in all eyes in group II after stabilization of refraction. No vitreous loss was encountered, and foldable IOL was implanted in the bag in all cases.

| Table 1 Age and sex distribution between the studied groups |
|-----------------|-----------------|-----------------|
| Group I         | Group II        | $t$-test $P$    |
| Age 55.4±14.38  | 54.35±13.66     | 0.237 0.814     |
| Sex $n$ (%)     |                 |                 |
| Female 11 (55.0)| 12 (60.0)       | 0.102 0.74      |
| Male 9 (45.0)   | 8 (40.0)        |                 |
| Total 20 (100.0)| 20 (100.0)      |                 |

Group I, the triple group; group II, the sequential group. $P>0.05$ is nonsignificant.

There was no statistically significant difference between the mean preoperative UCVA (0.012±0.009 in group I and 0.009±0.09 in group II; $P=0.873$). In group I, the mean postoperative UCVA at the first, third, sixth, ninth month, and 1 year postoperatively was 0.03±0.017, 0.058±0.018, 0.098±0.032, 0.14±0.06, and 0.21±0.07, respectively. The mean postoperative UCVA in the second group at the same follow-up period was 0.04±0.02, 0.11±0.041, 0.19±0.06, 0.24±0.09, and 0.27±0.07, respectively ($P=0.009$) (Fig. 1).

The mean postoperative best corrected visual acuity (BSCVA) in the first group at first, third, sixth, ninth month, and 1 year postoperatively was 0.05±0.03, 0.11±0.06, 0.17±0.09, 0.26±0.13, and 0.35±0.13, respectively. The mean postoperative BSCVA in the second group at the same follow-up periods was 0.27±0.05, 0.31±0.09, 0.35±0.14, 0.43±0.14, and 0.52±0.12, respectively ($P=0.021$). The percentage of change was also significantly higher in group I ($P=0.00$) (Fig. 2).

Figure 1

Line graph shows the mean preoperative uncorrected visual acuity and the uncorrected visual acuity at 1, 3, 6, and 9 months and 1 year postoperatively. Group I: the triple group. Group II: the sequential group.

Figure 2

Line graph shows the mean best corrected visual acuity at 1, 3, 6, and 9 months and 1 year postoperatively. Group I: the triple group. Group II: the sequential group. Data were expressed as mean±SD. *$P<0.05$ is statistically significant.
There were nine (45%) eyes with BSCVA greater than or equal to 0.5 in group I, and there were 12 (60%) eyes with BSVA greater than or equal to 0.5 in group II ($P = 0.14$).

The postoperative mean spherical equivalent (MSE) in group I at first, third, sixth, ninth month, and 1 year postoperatively was $-4.72\pm1.26$, $-3.62\pm0.74$, $-2.5\pm0.56$, $-1.9\pm0.38$, and $-1.6\pm0.2$, respectively. The mean postoperative spherical equivalent in group II at the same follow-up periods was $-2.6\pm1.23$, $-1.7\pm0.71$, $-0.8\pm0.51$, $-0.43\pm0.4$, and $-0.29\pm0.24$, respectively ($P = 0.00$). Percentage of decrease was significantly higher among group 2 ($P = 0.001$).

The postoperative mean cylinder (MC) in group I at the first, third, sixth, ninth month, and 1 year postoperatively was $-6.41\pm1.57$, $-5.67\pm1.57$, $-5.17\pm1.44$, $-4.65\pm1.25$, and $-3.85\pm1.21$, respectively. The postoperative MC in group II at the same follow-up periods was $-5.12\pm0.62$, $-4.82\pm0.63$, $-4.05\pm0.79$, $-3.71\pm0.75$, and $-3.45\pm0.82$, respectively. Although group II had a lower value, $P$ value between the two groups was 0.231, which was statistically insignificant.

In this study, although the number of eyes within $\pm 2$ D of the target refraction was higher in the second group (10 (50%) eyes in group I vs 14 (70%) eyes in group II), this difference was not statistically significant ($P = 0.19$).

There was no statistically significant difference between the mean ECC in the corneal graft implanted in both groups (2684.6±187.5 in group I vs 2701.5±197.3 in group II; $P = 0.089$). The mean ECC in the group I at the first, third, sixth, ninth month, and 1 year was 2189.2±180.19, 2155.7±265.7, 1909.2±250.6, 1781.0±258.8, and 1688.5±260.7, respectively, whereas the mean ECC in the group II at the first, third, sixth, ninth month, and 1 year was 2021.7±140.09, 1901.6±225.7, 1829.0±225.56, 1704.0±212.2, and 1665.4±196.2, respectively. There was no statistically significant difference between the mean ECC at the end of the follow-up period in both groups ($P = 0.524$). Although the percentage of endothelial cell loss at the end of the follow-up period was higher in group II, there was no statistically significant difference between both groups ($P = 0.412$) (Table 2).

There was early onset of PCO in one (5%) eye in group I treated by Yag capsulotomy after 3 months, one (5%) eye had captured IOL, and one (5%) eye had residual lens matter and loose stitch. This patient was prepared for second intervention when removal of the residual lens matter was done by I/A, and the stitch was removed and wound was resutured. One (5%) eye had an attack of endothelial rejection treated by intense topical and systemic steroid and subconjunctival triamcinolone acetonide injection. Apart from two (10%) eyes that developed PCO, no postoperative complication was noted in group II. There was no significant association or difference regarding the distribution of complications ($P = 0.34$), but the overall complication was significantly associated with group 1 ($P = 0.045$).

**Discussion**

In many patients, the corneal opacity and cataract coexist. Such patients are commonly approached by performing the triple procedure or applying the sequential approach. In this study, the results between patients undergoing triple procedure and sequential surgery in terms of VA, refractive outcome, ECC, and complications were compared.

In this study, the mean postoperative BSCVA in the triple group at one year postoperatively was 0.35±0.13, whereas the mean postoperative BSCVA in the sequential group at the same follow-up period was 0.52±0.12. Cazabon et al. [2] in 2010 found similar results with mean postoperative BCVA was 0.40 in the triple procedure group and 0.588 in the sequential surgery group.
Nine of 20 (45%) eyes gained BSCVA greater than or equal to 0.5 in the triple group. Javadi, Feizi, and Moein in 2013 had comparable results, with 40.8% of eyes gained BSCVA greater than or equal to 0.5 [3].

Nguyen et al. [1] in a large retrospective study involved 858 triple procedures and found that 61% of eyes attained BCVA of greater than or equal to 0.5. In the sequential group, 12 of 20 eyes (60%) gained BSCVA greater than or equal to 0.5. Hsiao et al. [4] reported BCVA greater than or equal to 0.5 in 21 (81%) eyes after selective suture removal and performing relaxing corneal incisions in 23% of the cases.

Parmar et al. [9] reported final visual outcome, where 39 and 47% of their patient achieved BCVA greater than or equal to 0.5 in the triple and the sequential group, respectively; this can be explained by the indication of surgery which was therapeutic keratoplasty after infective ulcer, and the patient in the triple procedure had repeated keratoplasty.

The postoperative MSE was −1.6 D in the triple procedure group at the end of the follow-up period, whereas in the sequential group was −0.29 D. The MSE was significantly lower in the sequential group. Nguyen et al. [1] in 2009 found similar results, with the MSE after 1 year of follow-up was 1.20 in the triple group and 0.08 D in the sequential group. Gruenauer-Kloevekorn et al. [7] reported MSE of −2.06 after the triple procedure and 0.70 after sequential surgery.

This study revealed that 10 (50%) eyes in the triple group were within ±2 D of emmetropia after 1 year of follow-up, and this compares favorably with other studies. Nguyen et al. [1] reported 47% of eyes achieved this after 1 year, with 55% achieving this at the end of the second year. Pineros et al. [10] reported 42% and Hayashi and Hayashi [5] had 39% of the eyes within ±2 D of the target emmetropia.

A total of 14 (70%) eyes in the sequential group achieved ±2 D of emmetropia at the end of the follow-up period. Other studies showed comparable results. Nguyen et al. [1] reported 67% of eyes achieved this after 1 year, with 50% achieving this at the end of the second year. Lower percent in the second year was explained by the low numbers of eyes with complete follow-up data. Pineros et al. [10] reported that 48% were within this value and Hayashi and Hayashi [5] had 70% of the eyes within ±2 D of the target emmetropia.

Geggel [11] performed IOL implantation alone at an average period of 11 months after PKP and ECCE. He reported that 95% of eyes were within ±2 D of emmetropia, but 59% of eyes in this series received astigmatic correction at the time of secondary surgery, and all graft corneal sutures had been removed in 86% of eyes. Moreover, Shimmura et al. [6] had similar results, with 91% of eyes were within ±2 D of emmetropia after manipulation of the single running suture placed at the time of PKP.

The MC at the end of follow up was −3.85±1.21 D in the triple group and −3.45±0.82 D in the sequential group. There was no statistically significant difference between both groups. Shimmura et al. [6] found that the manifest astigmatism at the end of follow-up was 3.4±1.1 D in the triple group and 2.4±1.2 D in the sequential group. Parmar et al. [9] reported an astigmatic error of −4.0±1.6 D in the triple procedure and −2.7±0.8 D in the sequential group, with no significant difference between the two groups. In contrast, Pineros et al. [10] in their comparative study revealed that the mean astigmatic error in the triple group was 3.9 D, whereas in the nonsimultaneous group was 4.1 D.

Toric IOL were not used in this study because they were not available in our institute. However, toric IOL should be considered in the management of the astigmatic error in the sequential group as reported by other studies [12,13].

The mean ECC recorded from the graft before performing PKP in both groups was 2684.6±187.5 and 2701.5±197.3 in the triple and the sequential groups, respectively. Because ECC had already decreased by the time of sequential cataract surgery, the mean ECC was 2151.2±40.2. The mean ECC measured at the end of follow-up period was 1618.5 ±260.7 in the triple group and 1665.4±196.2 in the sequential group, with no significant difference between them. The percentage of endothelial cell loss in the first group after 1 year was 35.6±5.85%, whereas in the second group was 36.87±6.21%.

Shimmura et al. [6] reported similar results with endothelial cell density measured at one year postoperatively was 1617±638 in the secondary group and 1675±866 in the triple group. It is worth noting that in this study, the surgeon used a cohesive viscoelastic, and the study was discontinued for ethical purpose with the introduction of dispersive viscoelastics, which offer a better endothelial protection. Hayashi and Hayashi [5] in their study...
ended with mean endothelial cell density of 1751±526 in the simultaneous group and 1651±636 with insignificant difference between both groups. In the sequential group, the ECC has already decreased by 20.3% by the time of cataract surgery; therefore, the endothelial density tended to be lower in the sequential group. However, the difference between the groups was not significant. The percentage of endothelial cell loss from that seen before cataract surgery was 11% at 3 months and 14.9% at 6 months, which was slight. These results indicate that secondary phacoemulsification surgery did not cause severe damage to the endothelial cells of the transplanted cornea. Hayashi and Hayashi [5] in 2006 reported 5.9% of endothelial cell loss at 3 months and 11.6% at 6 months after sequential surgery.

In the new approach suggested by Solaiman et al. [14] in 2019, simultaneous PKP and cataract surgery was done, followed by implantation of foldable three-piece acrylic IOL in the ciliary sulcus after removal of corneal sutures. They reported that the mean percentage of endothelial cell loss after IOL implantation was 7.3% at 6 months. However, the mean interval between cataract extraction and secondary IOL implantation was 13.3±2.2 months (range: 10–17 months), whereas in this study, cataract extraction and IOL implantation was done early after 6 months, so our results were more affected by the continuous decline in ECC after PKP.

Surgeons who do not favor the combined approach claim that the intraoperative risks are higher compared with sequential surgery, particularly because the open sky period is longer. It is hard to determine the exact rate of vitreous loss and posterior capsule rupture associated with the triple procedure. Some studies report a posterior capsule tear rate as high as 15% and vitreous loss of 4–12% [15], whereas others have reported a posterior capsule rupture rate of less than 1% [16]. In a more recent study, they reported one (1.3%) eye with vitreous loss following IOL implantation owing to positive vitreous pressure which necessitated automated anterior vitrectomy and exchange of the IOL with an angle-supported anterior chamber IOL [5]. In our study, despite limited patient number, we did not have any episodes of vitreous loss, posterior capsule rupture, or suprachoroidal hemorrhage in either group, so both procedures were equally safe.

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Conflicts of interest
There are no conflicts of interest.

References