Piggyback Intraocular Lens Implantation to Correct Pseudophakic Refractive Error After Segmental Multifocal Intraocular Lens Implantation

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ABSTRACT

PURPOSE: To evaluate refractive and visual outcomes of secondary piggyback intraocular lens implantation in patients diagnosed as having residual ametropia following segmental multifocal lens implantation.

METHODS: Data of 80 pseudophakic eyes with ametropia that underwent Sulcoflex aspheric 653L intraocular lens implantation (Rayner Intraocular Lenses Ltd., East Sussex, United Kingdom) to correct residual refractive error were analyzed. All eyes previously had in-the-bag zonal refractive multifocal intraocular lens implantation (Lentis Mplus MF30, models LS-312 and LS-313; Oculentis GmbH, Berlin, Germany) and required residual refractive error correction. Outcome measurements included uncorrected distance visual acuity, corrected distance visual acuity, uncorrected near visual acuity, distance-corrected near visual acuity, manifest refraction, and complications. One-year data are presented in this study.

RESULTS: The mean spherical equivalent ranged from -1.75 to +3.25 diopters (D) preoperatively (mean: +0.58 ± 1.15 D) and reduced to -1.25 to +0.50 D (mean: -0.14 ± 0.28 D; $P < .01$). Postoperatively, 93.8% of eyes were within ±0.50 D and 98.8% were within ±1.00 D of emmetropia. The mean uncorrected distance visual acuity improved significantly from 0.28 ± 0.16 to 0.01 ± 0.10 logMAR and 78.8% of eyes achieved 6/6 (Snellen 20/20) or better postoperatively. The mean uncorrected near visual acuity changed from 0.43 ± 0.28 to 0.19 ± 0.15 logMAR. There was no significant change in corrected distance visual acuity or distance-corrected near visual acuity. No serious intraoperative or postoperative complications requiring secondary intraocular lens removal occurred.

CONCLUSIONS: Sulcoflex lenses proved to be a predictable and safe option for correcting residual refractive error in patients diagnosed as having pseudophakia.

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Postoperative emmetropia plays a crucial role in multifocal intraocular lens (IOL) performance. Although continuous improvements in biometry techniques and lens formulas have led to a decreased rate of refractive surprises after cataract and clear lens extraction, refractive error due to a postoperative refractive shift is not always avoidable. Surgical options for treating pseudophakia and ametropia include lens exchange,[1,2] excimer laser surgery,[3-5] or implantation of a secondary (piggyback) IOL.[6-13] Although an exchange of an in-the-bag IOL may be chosen for early detected and large amounts of ametropia (eg, due to incorrect lens power placement), it is surgically traumatic and less predictable for a late postoperative refractive shift. Using excimer lasers enhances postoperative refractive results. However, it may not be appropriate for everyone due to a higher prevalence of dry eyes in the older population.[14-16] Using a secondary (piggyback) IOL to correct pseudophakia and ametropia is not always free of complication; intralenticular opacification and Elshnig pearls formation,[17-20] raised intraocular pressure, pigment dispersion, and pupillary block glaucoma[21-24] have occurred. Most complications relate to placing a secondary lens in the capsular bag or using a conventional IOL designed for in-the-bag fixation in the cilliary sulcus.

The Sulcoflex aspheric 653L lens (Rayner Intraocular Lenses Ltd., East Essex, United Kingdom) was specifically designed for cilliary sulcus fixation and correction of pseudophakia and ametropia. It is a one-piece, hydrophilic acrylic IOL with a 14.0-mm overall diameter, 6.5-mm optic diameter, and 10° haptic angulation. The optic has a convex-concave configuration and both the optic and haptics have round and smooth edges. We present refractive and visual outcomes of Sulcoflex

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lens implantation to correct postoperative refractive error in patients with a multifocal lens implantation.

PATIENTS AND METHODS

Eighty pseudophakic eyes that became ametropic following multifocal IOL implantation (Lentis Mplus MF30; Oculentis GmbH, Berlin, Germany) of 64 patients were included in this retrospective study. Patients were from a database of approximately 20,000 eyes implanted with Lentis Mplus lenses in our practice in which a small percentage of eyes became ametropic postoperatively. Although excimer lasers are normally used, the piggyback technique seemed to be a better option for these 80 cases because of the fear of worsening dry eye syndrome following laser ablation. The Sulcoflex lens was implanted in the cilliary sulcus to correct residual refractive error. Patients with a history of glaucoma, retinal detachment, corneal disease, neuro-ophthalmic disease, macular degeneration, or retinopathy were excluded during the original in-the-bag multifocal IOL implantation. Exclusion criteria for the IOL implantation were history of prolonged iritis, uveitis, cystoid macular edema or uncontrolled intraocular pressure following the original lens exchange surgery, zonular defects that could prevent good fixation of the Sulcoflex lens, and a refractive cylinder of more than 1.0 diopter (D). The minimum time interval between the original lens exchange and the Sulcoflex lens implantation was 6 months. Two stable preoperative refractions (measured 3 months apart) were necessary prior to piggyback lens insertion. Informed consent was obtained from all patients.

Preoperative measurements included uncorrected distance visual acuity, uncorrected near visual acuity, corrected distance visual acuity, distance-corrected near visual acuity, endothelial cell count (SP 2000P Specular Microscope; Topcon Medical Systems, Inc., Oakland, NJ), biometry (IOLMaster; Carl Zeiss Meditec AG, Jena, Germany), autorefraction and tonometry (Tonoref II; Nidek Co., Ltd., Fremont, CA), subjective refraction, slit-lamp evaluation, and dilated funduscopy. Visual acuity was measured at a distance with a Snellen visual acuity chart and recorded in meter (6/_) equivalent.

The Sulcoflex lens calculation was performed using the manufacturer's web-based program (http://www.rayner.com/raytrace/). Although biometry (ie, axial length, anterior chamber depth, and keratometry) was repeated in all cases, manifest refraction was the most important variable in the Sulcoflex lens calculation. Surgically induced astigmatism was included in the calculation depending on the amount of preoperative refractive cylinder. The new incision was made on the steepest axis according to the refraction meridian to neutralize existing astigmatism and achieve the best possible postoperative result. A superior incision was made in patients with no refractive cylinder.

Surgical Technique

Two surgeons equally performed the surgeries (JV, AO). The patient was seated at the slit lamp with vertical head alignment and the corneal limbus was marked at the 270° position with a sterile disposable ink pen (Devon Fine Skin Marker; Tyco Healthcare Ltd., Gosport, United Kingdom). Sub-Tenon anesthetic block was performed and the patient was prepared and draped for surgery. The steep meridian was marked intraoperatively with a Mendez gauge (Duckworth and Kent Ltd., Baldock, United Kingdom) with the aid of preoperatively marked reference points. A 2.75-mm clear corneal incision was made and the anterior chamber was filled with Artivisc 1% (Ophtec BV, Boca Raton, FL). The Sulcoflex lens was implanted in the ciliary sulcus using a single-use, one-piece injector supplied by the manufacturer. The ophthalmic viscosurgical device was flushed out and cefuroxime 1.0 mg in 0.1 mL was intracamerally injected.

Postoperatively, patients were instructed to instill one drop of antibiotic levofloxacin 0.5% (Oftaquix; Santen GmbH, Germering, Germany) four times daily for 2 weeks, one drop of steroidal anti-inflammatory 0.1% dexamethasone (Maxidex; Alcon Laboratories, Inc., Fort Worth, TX) four times daily for 2 weeks, and one drop of nonsteroidal anti-inflammatory ketorolac trometamol 0.5% (Acular; Allergan, Inc., Irvine, CA) four times daily for 1 month.

Statistical Analysis

Visual acuity measurements were converted to logMAR for statistical analysis. The Wilcoxon rank–sum test was used to compare preoperative and postoperative refractive and visual acuity outcomes. Summary statistics (eg, means and standard deviations) were presented to describe the study population. All data were analyzed using the Microsoft Office Excel 2007 program (Microsoft Corp., Redmond, WA) and Statistica 6 (StatSoft, Inc., Tulsa, OK). A *P* value of less than .05 was considered statistically significant.

RESULTS

Eighty eyes of 64 patients treated between December 2010 and February 2012 were included in this study. Male-to-female ratio was 48.4%:51.6%. The implanted Sulcoflex lens power ranged from -2.50 to +4.5 D (**Figure 1**). Preoperative and postoperative statistics are summarized in **Table 1**. One-year data are presented in this study.

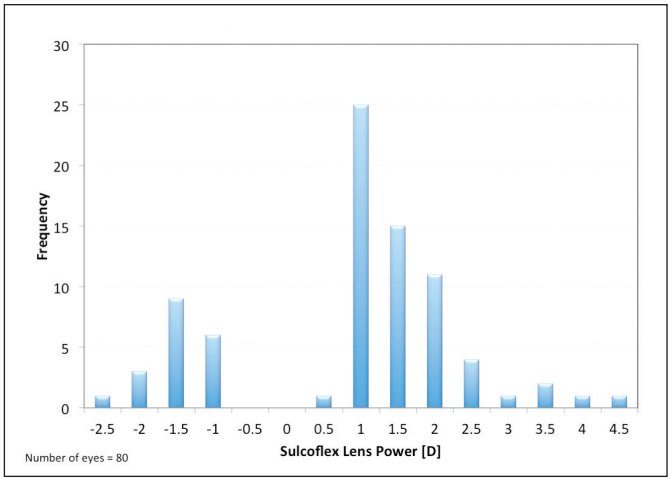

Figure 1. Preoperative lens power distribution in 80 consecutive eyes implanted with the Sulcoflex aspheric 653L intraocular lens (Rayner Intraocular Lenses Ltd., East Sussex, United Kingdom).

Refractive Outcome

Both sphere and cylinder reduced significantly postoperatively (**Table 1**). **Figure 2** compares the preoperative and postoperative spherical equivalent. Postoperatively, 93.8% of eyes were within ±0.50 D and 98.8% were within ±1.00 D of emmetropia.

Figure 3 plots the predictability of spherical equivalent. The tight distribution of data points grouped between ±0.50 lines indicated a good predictability (R^2: 0.94). The mean postoperative spherical equivalent was slightly myopic, which is also observed on the linear regression line in **Figure 3**.

Visual Acuity

There was a statistically significant improvement in uncorrected distance visual acuity. Postoperatively, 78.8% of eyes achieved an uncorrected distance visual acuity of 6/6 (Snellen 20/20) or better (0.0 logMAR) and 88.8% achieved 6/5 (Snellen 20/16) or better (0.1 logMAR). **Figure 4** compares preoperative and postoperative uncorrected distance visual acuity. Corrected distance visual acuity remained mostly unchanged with no eyes losing two or more lines (**Figure 5**). The change in mean corrected distance visual acuity was not statistically significant ($P = .56$).

The mean uncorrected near visual acuity improved significantly. There was no statistically significant change in the mean distance-corrected near visual acuity.

TABLE 1
Preoperative and Postoperative Characteristics (N = 80)

Characteristic	Preoperative	Postoperative	P[a]
Lens power of Lentis Mplus MF30 (LS-312 & LS-313) implant (D)			
Mean ± SD	22.25 ± 4.14	–	–
Range	11.5 to 36.0	–	–
Lens power of Sulcoflex 653L implant (D)			
Mean ± SD	0.88 ± 1.51	–	–
Range	-2.5 to 4.5	–	–
Age at time of surgery (y)			
Mean ± SD	59.8 ± 8.19	–	–
Range	41 to 81	–	–
Sphere (D)			
Mean ± SD	0.85 ± 1.21	0.03 ± 0.28	< .01
Range	-1.50 to 3.75	-0.75 to 0.75	
Cylinder (D)			
Mean ± SD	-0.54 ± 0.32	-0.33 ± 0.34	< .01
Range	-1.00 to 0.00	-1.50 to 0.00	
Spherical equivalent (D)			
Mean ± SD	0.58 ± 1.15	-0.14 ± 0.28	< .01
Range	-1.75 to 3.25	-1.25 to 0.50	
CDVA (logMAR)			
Mean ± SD	-0.03 ± 0.06	-0.04 ± 0.06	.56
Range	-0.1 to 0.1	-0.1 to 0.1	
UDVA (logMAR)			
Mean ± SD	0.28 ± 0.16	0.01 ± 0.10	< .01
Range	0.1 to 0.7	-0.1 to 0.3	
DCNVA (logMAR)			
Mean ± SD	0.18 ± 0.13	0.19 ± 0.14	.38
Range	-0.1 to 0.4	-0.1 to 0.4	
UNVA (logMAR)			
Mean ± SD	0.43 ± 0.28	0.19 ± 0.15	< .01
Range	-0.2 to 0.9	-0.1 to 0.5	

D = diopters; SD = standard deviation; CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity; DCNVA = distance-corrected near visual acuity; UNVA = uncorrected near visual acuity
[a]*Wilcoxon signed–rank test.*
The Lentis Mplus MF30 multifocal intraocular lens is manufactured by Oculentis GmbH, Berlin, Germany, and the Sulcoflex 653L intraocular lens is manufactured by Rayner Intraocular Lenses Ltd., East Sussex, United Kingdom.

Complications

There were no intraoperative complications. Postoperative complications included three cases of iritis that persisted longer than 1 month and were successfully resolved with the use of topical steroids. Raised intraocular pressure that persisted longer than 2 weeks postoperatively was recorded in 7 patients and resolved within the first 6 weeks in all cases. One patient had a slightly oval pupil on slit-lamp examination, which was not cosmetically noticeable and still mobile and reactive to light. One patient reported occasional

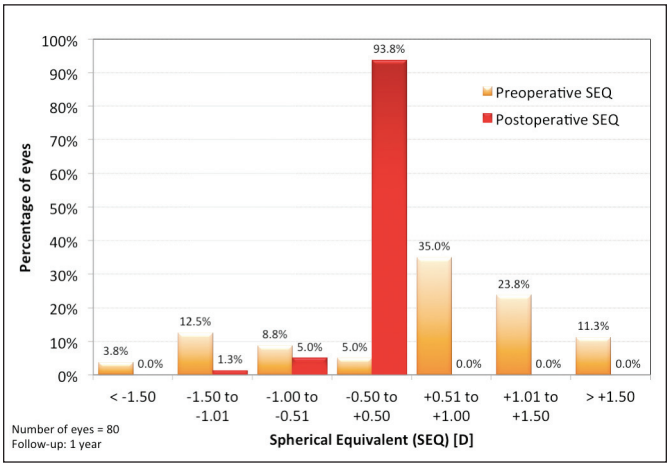

Figure 2. Refractive outcome: preoperative and postoperative spherical equivalent (SEQ).

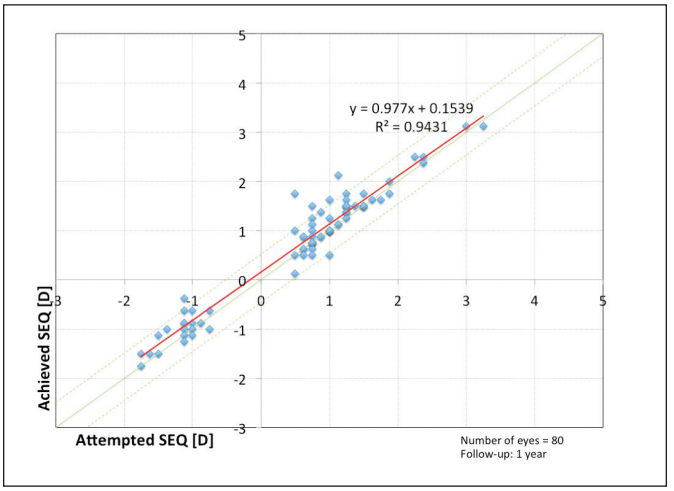

Figure 3. Predictability of spherical equivalent (SEQ).

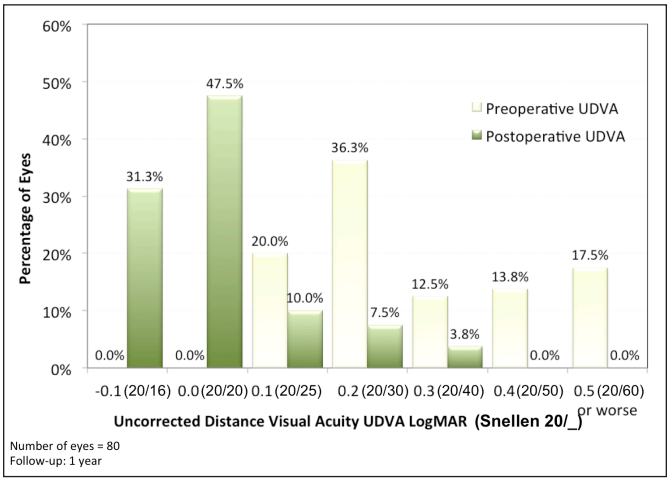

Figure 4. Comparison of preoperative and postoperative uncorrected distance visual acuity (UDVA).

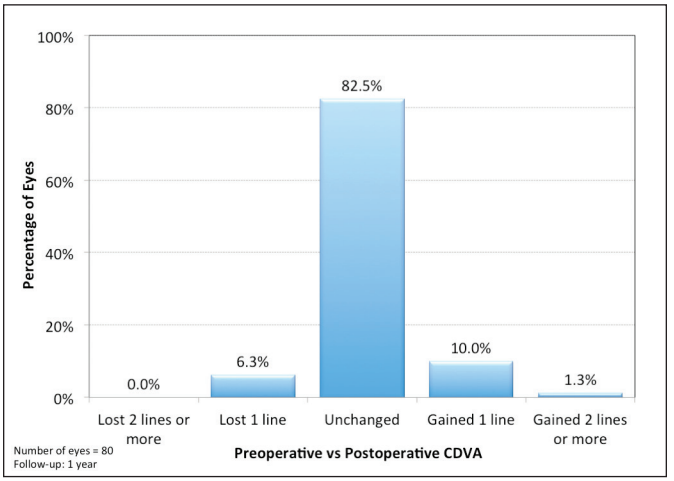

Figure 5. Safety: comparison of preoperative and postoperative corrected distance visual acuity (CDVA).

yellow line or reflection in vision since the secondary intraocular lens implantation, but did not find it significant enough to warrant a lens removal. Four patients had slightly more myopic results than expected, but the refraction was still correctable to a minimum of 6/6 (Snellen 20/20, 0.0 logMAR). One patient had an unexpected postoperative cylinder of -1.50 D due to change in the corneal shape from the incision, but achieved 6/5 (Snellen 20/16, -0.1 logMAR) with spectacle correction.

DISCUSSION

Patients undergoing clear lens extraction or cataract surgery with a multifocal IOL have high expectations for visual and refractive outcomes. Even a small amount of refractive error may greatly influence multifocal IOL performance and lead to patient dissatisfaction.[25] Although every care should be taken to minimize the possibility of incorrect lens power implantation and preoperative biometry errors, surgeons cannot always influence a late postoperative refractive shift caused by changes in IOL position. Many factors, including capsular fibrosis, capsulorhexis size, lens material, and haptic and optic design, are known to influence postoperative effective lens position.[26-31] Errors in cataract surgery are also dependent on the accuracy of lens power formulas. A recent large-population study[32] evaluating the most commonly used IOL formulas found only 75% of eyes were within ±0.50 D of their target refraction, despite using the optimized A-constant.

In the current study, there was a minimum of 6 months between in-the-bag placement of a multifocal IOL and supplementary Sulcoflex lens implantation to ensure no further refractive change. Refractive stability had to be evident for at least 3 months before consideration of a piggyback IOL.

To our knowledge, there are three studies evaluating refractive performance of the Sulcoflex lens; however,

the patient cohorts are small. In the prospective study by Kahraman and Amon,[10] the Sulcoflex 653L IOL was implanted in 12 pseudophakic eyes with ametropia and achieved a postoperative spherical equivalent of -0.25 ± 0.40 D and an uncorrected distance visual acuity of 0.9 ± 0.1 (approximately 0.05 logMAR). Khan and Muhtaseb[11] presented results of 5 eyes: 4 eyes underwent Sulcoflex 653F multifocal supplementary IOL implantation and all achieved a postoperative spherical equivalent within ±0.50 D. The remaining eye had a toric Sulcoflex 653T lens implanted with a resulting refraction of -0.50 -1.00 × 80. Falzon and Stewart[12] retrospectively evaluated the results of 3 eyes with the Sulcoflex 653L IOL and 12 eyes with the Sulcoflex 653T toric IOL and achieved a postoperative mean spherical equivalent of -0.15 ± 0.28 D. All eyes in the study achieved an uncorrected distance visual acuity of 0.2 logMAR or better.

The predictability of refractive correction and efficacy of these studies is comparable to our study with the spherical equivalent of -0.14 ± 0.28 D and mean uncorrected distance visual acuity of 0.01 ± 0.10 logMAR. We achieved a mean unaided near visual acuity of 0.19 ± 0.15 logMAR with the combination of the Lentis Mplus lens in the capsular bag and the Sulcoflex lens in the cilliary sulcus. This is slightly better than the mean uncorrected near visual acuity in our recent study of 9,366 eyes with the Lentis Mplus lens (0.22 ± 0.18 logMAR).[33] This could be attributed to the fact that 6.3% of eyes in the current study had a slightly myopic spherical equivalent. In theory, additional implants can affect the multifocality, reading performance, or quality of vision of the original multifocal lens. This would be interesting to investigate, but was not the aim of this study.

The piggyback implantation technique has recently evolved and the complication rate has been reduced with improved supplementary IOL designs and their placement in the cilliary sulcus rather than the capsular bag. Previous reports of intralenticular opacification were mostly related to the lens materials of the two IOLs, capsulorhexis size, and the placement of both primary and supplementary IOLs in the capsular bag.[16-19] However, intralenticular opacification was mostly observed in the late postoperative period (1 to 2 years). There were no cases of intralenticular opacification at the 1-year follow-up, but long-term data would be beneficial in this respect. Postoperative elevated or uncontrolled intralenticular opacification has also been a concern with the piggyback technique.[21-24] Most case reports relate to placement of a square-edged or inappropriately sized IOL in the cilliary sulcus and consequent chafing of the posterior surface of the iris. We reported seven cases of raised intraocular pressure, but all were related to the use of postoperative steroids rather than the Sulcoflex lens design and were resolved within 6 weeks postoperatively.

The Sulcoflex lens was designed to overcome the main placement issues of a secondary IOL in the cilliary sulcus. It has a relatively large optic and overall diameter and both round and smooth optic and haptic edges. The haptics are designed with a 10° posterior angulation in relation to the optics and should therefore provide appropriate distance from uveal tissues and the IOL in the capsular bag.

To our knowledge, there are two studies that have evaluated position, stability, and interaction of the Sulcoflex lens with intraocular structures. Kahraman and Amon[10] measured anterior chamber inflammation with a laser flare cell meter in 12 eyes with a follow-up period of 17 months. They also used Scheimpflug imaging, ultrasound biomicroscopy, and a digital slit-lamp camera to evaluate IOL position and centration, distance between the iris and secondary intraocular lens, distance between the primary and secondary IOL, haptic position, and pigment dispersion. No signs of pigment dispersion, iris bulging, foreign body giant cell formation, or intralenticular opacification were observed during the follow-up period. Decentration of the secondary IOL of less than 0.5 mm at day 1 occurred in one eye and remained stable throughout the follow-up period. The authors found no cases of IOL rotation or tilt.

McIntyre et al.[34] implanted the Sulcoflex lens in 11 pseudophakic human cadaver eyes and used high-frequency ultrasound to assess IOL fixation, centration, tilt, and clearance with intraocular structures and primary IOL. The Sulcoflex lens showed an appropriate centration, minimum or no tilt in all eyes, and appropriate distance from the primary IOL. Direct assessment of the sulcus-fixated haptics from different perspectives showed no disturbances to the ciliary processes. Although the purpose of the current study was to evaluate visual and refractive outcomes with the piggyback technique, no cases of lens tilt and rotation, dislocation, or decentration were observed.

The Sulcoflex lens is an alternative for correcting residual pseudophakia and ametropia in patients who cannot undergo excimer laser ablation. The main advantages are predictability with lens calculation being dependent on postoperative refractive measurements, low complication rate, and theoretical reversibility of the procedure. Supplementary IOL implantation did not affect the reading performance of the original in-the-bag multifocal IOL; there was no statistically significant change in the preoperative and postoperative distance-

corrected near visual acuity. With an increased number of patients undergoing multifocal lens implantation as a refractive procedure, surgeons will face increased demands for correcting residual refractive error and the piggyback technique is one correction option.

AUTHOR CONTRIBUTIONS

Conception and design (JAV, SCS); data collection (AO, JAV, MP); analysis and interpretation of data (MP); writing the manuscript (MP); critical revision of the manuscript (AO, JAV, SCS)

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