Original Article

Spherical equivalent pre- and post-implantable collamer lens implantation in patients with myopia, hyperopia, and stable keratoconus

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Abstract:

PURPOSE: Refractive errors are common in Saudi Arabia and keratorefractive surgeries are usually done to correct them. However, not all patients are fit and complications postoperatively are a concern. Implantable collamer lens (ICL) implantation can be used for patients who are not fit for keratorefractive surgeries. ICL can also be used for keratoconus. We elected to evaluate the outcomes of patients who had ICL implantation for refractive errors or keratoconus.

METHODS: We retrospectively reviewed patients aged between 21 and 45 years old, who attended the anterior segment clinic at King Khaled Eye Specialist Hospital and who had spherical equivalent (SE) ranging between (+16 to −23 diopters), and had ICL implantation between February 2015 and September 2017. The SE was documented before and after the surgery. Depending on the SE, patients were divided into two groups (myopia and hyperopia). Statistical analysis was done to evaluate the change in mean SE before and after surgery for patients.

RESULTS: We identified 169 eyes and 155 (92%) were myopic before the surgery. Before surgery, the mean SE was −8.6 and the standard deviation (SD) was 4.4. Only 14 eyes (8%) were hyperopic before the surgery with a mean SE of +5.5 and SD of 4.8. The difference in the mean of SE between after and before the surgery for myopic eyes was statistically significant (mean difference: 7.8, SD: 5, $P < 0.0001$). The difference in the mean of SE between post- and pre-operatively was also significant for hyperopic eyes (mean difference: −6.1, SD: 5.2, $P = 0.0007$). In 32 eyes with keratoconus, the mean SE before surgery was −7.9 with an SD of 4.1. For the keratoconus eyes, the mean difference of SE between after and before surgery was statistically significant as the mean difference in SE was 7.2 with an SD of 4.6 ($P < 0.0001$).

CONCLUSION: The effect of ICL implantation was significant in improving the SE for myopic, hyperopic, and keratoconus eyes.

Keywords:

Implantable collamer lens implantation, keratoconus, refractive errors

Introduction

Refractive errors are common in Saudi Arabia, myopia being the most common.[1] Keratorefractive surgeries are used to correct refractive errors, however, not all patients are fit for these procedures due to high refractive errors or poor healing in the corneal epithelium. Furthermore, possible postoperative complications are a concern, especially corneal ectasia.[2] In 1950s Strampelli came up with the idea of designing a minus intraocular lens (IOL) to correct extreme myopia[3] and Barraquer conducted a study on those Polymethyl Methacrylate plate anterior chamber angle fixed phakic IOLs and found out that 60% of the IOLs had to be removed due to intraocular complications.[4] In mid-1980s, after the advancement of the operating microscope and the discovery of corneal endothelial function, Fechner and Baikoff modified the Worst iris claw lens and Kelman multiflex anterior chamber IOL, respectively.[5-7] One

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drawback of this model was the endothelial loss, but with several model modifications, they were able to overcome this problem.[8-11] In 1993, posterior chamber phakic IOL was introduced and was labeled as implantable contact lenses.[12] Because it is made of 60% poly-hydroxyethyl methacrylate, water (36%), benzophenone (3.8%), and 0.2% porcine collagen, tStaar (Monrovia, CA, USA). called it Collamer (collagen-copolymer).[12] Several studies have approved the efficacy of posterior chamber phakic IOL for correcting myopic astigmatism,[13] high to extreme myopia,[13-17] and refractive error in stable keratoconus.[18,19]

Methods

We retrospectively reviewed patients aged between 21 and 45 years old, who attended the anterior segment clinic at King Khaled Eye Specialist Hospital and who had spherical equivalent (SE) ranging between (+16 to −23 diopters), and had implantable collamer lens (ICL) implantation V4 surgery between February 2015 and September 2017. These patients were not fit for keratorefractive procedures, had stable refraction (<0.5 D in 1 year), had anterior chamber depth of more than 2.8 mm, and had endothelial cell count more than 2000 cells/mm^2. We also included the off-label use of ICL in stable keratoconus, corneal rings, and post-suture-less grafts (lamellar keratoplasty, Penetrating Keratoplasty) with regular astigmatism and stable refraction for at least 2 years.

Monocular patients, patients with preexisting pathology (cataract, zonular anomalies, lens subluxation, glaucoma, uveitis, post keratorefractive surgeries or vitreoretinal surgery), and narrow-angle were excluded from the study.

The baseline characteristics for patients were described. For continuous data, we used the mean, standard deviation (SD) and for categorical data, we used proportions (percentages). The SE was documented before and after the surgery. Depending on the SE, patients were divided into two groups (myopia and hyperopia). Wilcoxon signed-rank test was used to evaluate the change of mean SE before and after surgery. The percentage change in SE after the surgery was also documented in the myopia and hyperopia groups.

We also divided myopic eyes into three categories, based on the interquartile ranges. Group 1 included eyes who had an (SE from 0 to −5.75), Group 2 (SE from > −5.75 to −10.75), and Group 3 (SE from > −10.75 to −23). The Chi-square test was used to evaluate achieving > 90% change in SE after surgery between the myopia groups. Analysis of variance was used to compare the age between these different myopia groups. All tests were two-sided and a $P < 0.05$ was considered significant. Statistical analysis was done using JMP software version 14 (SAS, Cary, NC).

Results

We identified 169 eyes and 155 (92%) were myopic before the surgery. The distribution of the SE for these eyes is displayed in Figure 1. Before surgery, the mean SE was − 8.6 and the SD was 4.4. The lowest SE was −0.5 and the highest SE was −23. Only 14 eyes (8%) were hyperopic before the surgery with a mean SE of +5.5 and SD of 4.8. Figure 2 shows the distribution of the SE for the hyperopic eyes with the lowest SE being +0.25 and the highest SE being +16.1.

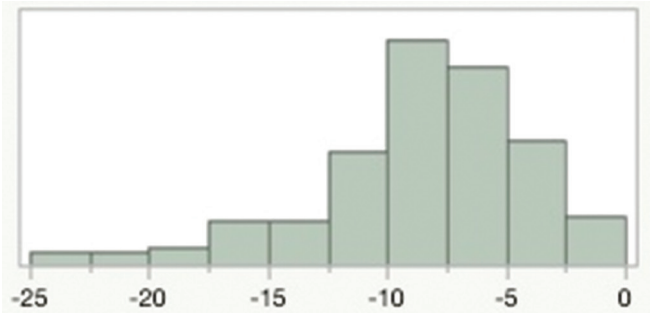

Figure 1: Histogram showing the SE before surgery for myopia patients. SE: Spherical equivalent

Postoperatively, the SE for myopic eyes has decreased [Figure 3] with a mean of −0.85 and SD of 2.3. Figure 4 displays the difference in SE between after and before surgery. The difference in the mean of SE between, after and before the surgery was statistically significant (mean difference: 7.8, SD: 5, $P < 0.0001$). On the other hand, eyes with hyperopia had a decrease in SE after surgery with a mean of − 0.6 and SD of 1.9) [Figure 5]. The difference in the mean of SE between pre- and post-operatively was also significant for hyperopic eyes (mean difference: −6.1, SD: 5.2, $P = 0.0007$) [Figure 6].

We also evaluated the percentage change in SE post-ICL. In myopic eyes, the mean SE change was 86%, with an SD of 49%. 79 (51%) of myopic eyes had more than 90% changes in their SE after surgery. For hyperopic eyes, the mean change of SE was 133% and the SD was 150%. 11 (78%) of hyperopic eyes had a change of their SE of more than 90%.

For myopic eye groups, eyes in Groups 2 and 3 were more likely to achieve >90% change in SE compared to Group 1. Specifically, 58% of Group 2 and Group 3 eyes had >90% change in SE compared to 28% in Group 1 ($P = 0.003$). There was no difference in age between the myopic eye groups ($P = 0.3$).

In 32 eyes with keratoconus, the mean SE before surgery was −7.9 with an SD of 4.1 [Figure 7] and postoperatively the mean SE was −0.7 with a SD of 2.1 [Figure 8]. For the keratoconus eyes, the mean difference of SE between, after and before surgery was statistically significant as the mean difference in SE was 7.2 with an SD of 4.6 ($P < 0.0001$) [Figure 9].

Discussion

Posterior chamber phakic IOL implantation has many advantages when compared to corneal laser-based refractive procedures and is considered a viable option for correction with possible preservation of accommodation. Numerous studies demonstrated the efficacy of posterior chamber phakic

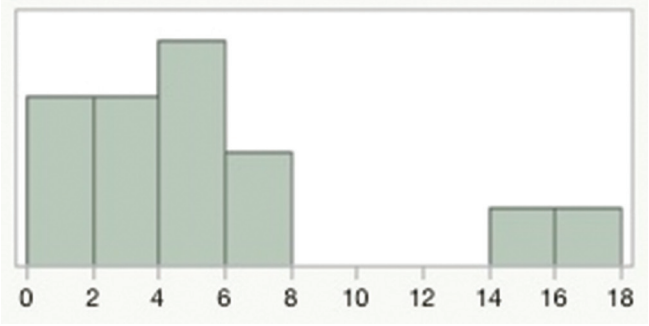

Figure 2: Histogram showing the SE before surgery for hyperopia patients. SE: Spherical equivalent

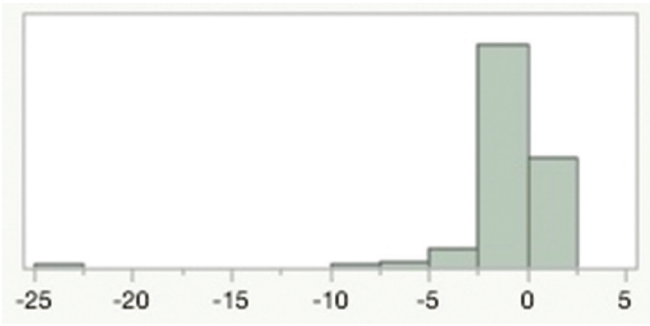

Figure 3: Histogram showing the SE after surgery for myopia patients. SE: Spherical equivalent

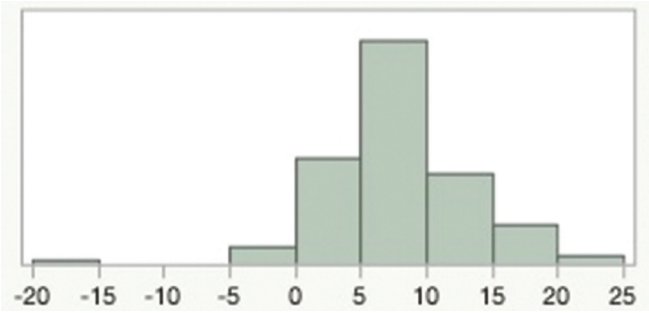

Figure 4: Histogram showing the difference in SE between post and pre-operatively for myopia patients. SE: Spherical equivalent

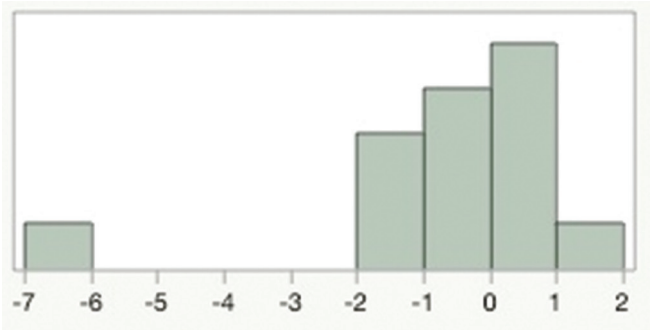

Figure 5: Histogram showing the SE after surgery for hyperopia patients. SE: Spherical equivalent

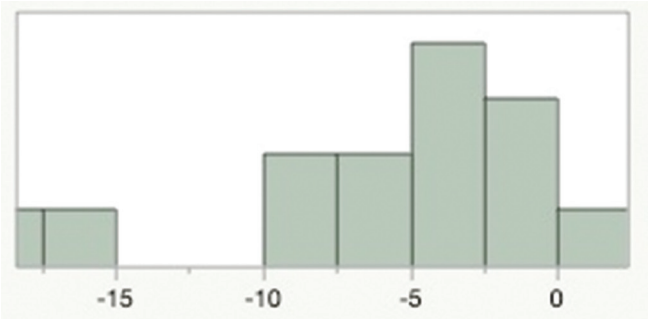

Figure 6: Histogram showing the difference in SE between post and pre-operatively for hyperopia patients. SE: Spherical equivalent

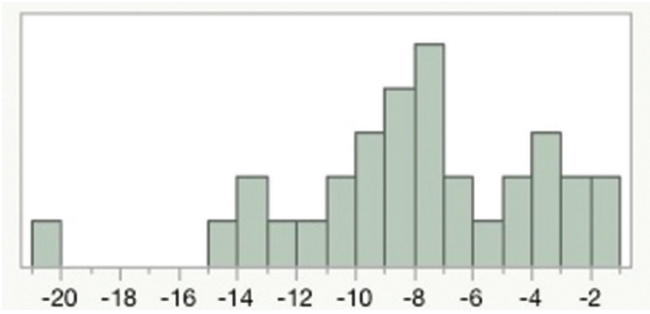

Figure 7: Histogram showing the SE for eyes with keratoconus before surgery. SE: Spherical equivalent

IOL for correcting, myopic astigmatism,[13] high to extreme myopia,[13-17] and refractive error in stable keratoconus[18,19]

In our study, the manifest SE (MSE) post-ICL (V4c) implant in the myopic eyes was −0.85 with an SD of 2.3. Pineda- Fernández *et al*., reported similar results in their myopic group where the MSE in 61.1% and 22% of eyes within ±1.00 D and ±0.50 D of emmetropia.[20] In their study, the mean residual sphere was −0.25 D. Furthermore, in other studies, insignificant refractive changes during follow-up after ICL implantation were noted.[21] In a series of 216 patients, a mean of −0.09 ± 1.06 D sphere post-ICL implantation for myopic eyes was found, and the mean preoperative sphere was −10.35 ± 5.1 D.[22]

Kocová *et al*. evaluated the Implantable collamer lens for hyperopia (ICH) V3 for hyperopic eyes on 22 patients and found a mean SE after 1 year of follow-up of + 0.35 D ± 0.86. At the last visit, it was + 0.73 D ± 0.93 but was not a statistically significant.[23] In our study, we had 14 eyes with hyperopia with a mean SE of +5.5 and an SD of 4.8 preoperatively. The lowest SE was +0.25 and the highest SE was +16.1. The difference in mean between post-and preoperatively was also significant for hyperopic eyes (mean difference: −6.1, SD: 5.2, $P = 0.0007$), but our ICL module was ICH (V4).

For ICL (V4c) implanted in stable keratoconus our mean SE before surgery was −7.9 with an SD of 4.1 and postoperatively the mean SE was −0.7 with a SD of 2.1. The mean difference for SE between after and before surgery was statistically significant as the mean difference in SE was 7.2 with SD of 4.6 ($P < 0.0001$). Emerah *et al*., reported encouraging similar results where the mean preoperative MSE decreased

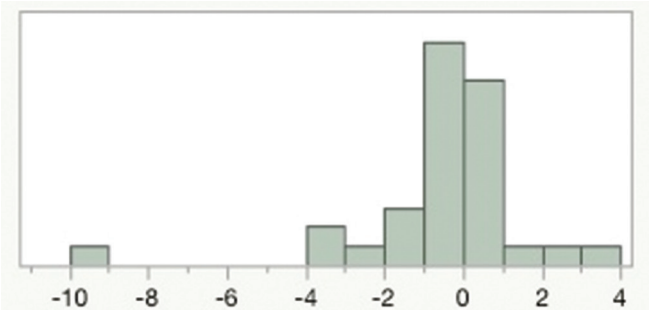

Figure 8: Histogram showing the SE for eye with keratoconus after surgery. SE: Spherical equivalent

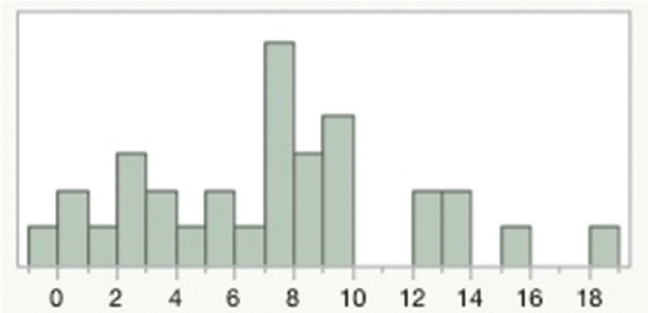

Figure 9: Histogram showing the difference in SE between post and preoperatively for keratoconus eyes. SE: Spherical equivalent

from −4.8 ± 2.25 to −0.3 ± 0.4 D and was statistically significant ($P < 0.01$). At 6 months after surgery the mean of their achieved SE was 74% of their attempted mean SE. Sixty-five percent of eyes were within ±0.75 D of the attempted SE correction and 85% were within ±1.0 D of the attempted SE correction. It is likely that their good visual outcome was related to the selection of regular cornea preoperatively where they excluded any Ksteep more than 52.0 D or surface regularity index more than 1.5.[18]

Conclusion

Our study has the limitations of the retrospective studies and our results were confined to pre- and post-ICL SE only. Despite this, we show that the surgical intervention was beneficial in our population, which was also found in some other studies. The results of ICL implants for myopic, hyperopia, and stable keratoconus correction were safe, effective, and predictable. A randomized clinical trial would be the most ideal to confirm the benefit of such intervention.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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