Outcomes of Implantable Collamer Lenses in Patients with Keratoconus: A Systematic Review and Meta-Analysis

ALKHABBAZ [1], M. KARAM [1,2], A. POLLMANN[3], A. LAU [2], H. AL-AWADHI [1], K. ABBAS [4], S. NATH [2], S. JABBOUR [2, 3, 5]

1 Al Bahar Eye Center, Ministry of Health, Kuwait City, Kuwait,; 2 Department of Ophthalmology and Visual Sciences, McGill University, Montreal, Quebec, Canada; 3 Department of Ophthalmology, Centre Hospitalier de l'Université de Montréal (CHUM), Montréal, Canada; 4 Faculty of Medicine, University of British Columbia, Vancouver, British Columbia, Canada; 5 T.H. Chan School of Public Health, Harvard University, Boston, Massachusetts, USA

INTRODUCTION

Implantable Collamer Lenses (ICLs) are intraocular lenses used to correct myopia, hyperopia, and astigmatism. They **maintain the eye's accommodation function, making them suitable for young patients with high refractive errors or those unsuitable for corneal laser procedures.**

Recently, there's been increased interest in using ICLs for keratoconus patients.

AIM

To evaluate vision outcomes and complications of ICL implantation in patients with keratoconus.

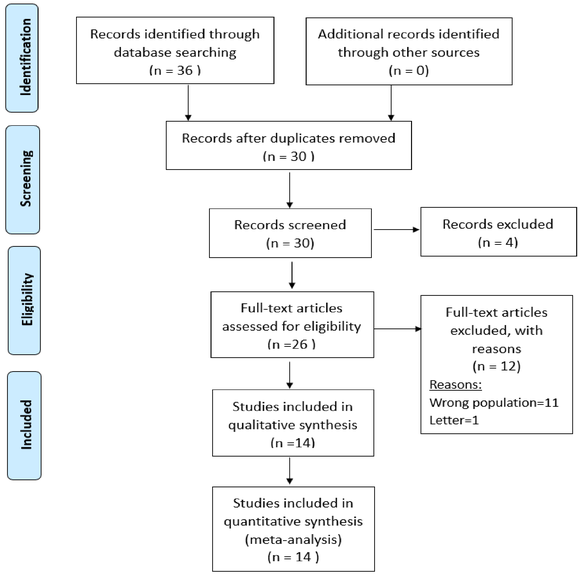
METHOD

- A systematic review and meta-analysis were conducted as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses **(PRISMA) guidelines**.
- Publications in **MEDLINE, EMBASE, EMCARE, CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL)** assessing efficacy of ICL for keratoconus were screened for eligibility.
- **Inclusion Criteria:** Only patients with no previous surgery for keratoconus or those who underwent corneal cross-linking alone (CXL) alone. All randomized control trials (RCTs) and observational studies assessing efficacy of ICL for keratoconus.
- **Exclusion Criteria:** Studies including intracorneal ring segments (ICRS), CXL + photorefractive keratectomy (PRK), and corneal allogenic intrastromal ring segments (CAIRS). Abstract only, conference literature, dissertation, and case reports.

RESULTS

14 included studies with a total sample size of **309 patients** and **397 eyes**

Figure 1 Prisma Flow Diagram: The PRISMA diagram details the search and selection processes applied during the overview.



Visian ICL/TICL (V4c and V4): STAAR Surgical, Nidau, Switzerland/ Monrovia, CA

*Figure 2 Forest plot for the **mean change in UDVA** post-operatively compared to pre-operative values at 6m and 1 y.*

Group by Time point	Study name	Statistics for each study						
		Mean	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Month 6	Emerah (2019)	0.620	0.046	0.002	0.529	0.711	13.394	0.000
Month 6	Antonios (2015)	1.400	0.086	0.007	1.231	1.569	16.216	0.000
Month 6	Shaheen (2014)	0.220	0.038	0.001	0.147	0.293	5.867	0.000
Month 6	Pooled	0.741	0.277	0.077	0.199	1.283	2.679	0.007
Month 6	Prediction Interval	0.741			-6.248	7.730		
Year 1	Antonios (2015)	1.400	0.086	0.007	1.232	1.568	16.315	0.000
Year 1	Shaheen (2014)	0.250	0.040	0.002	0.172	0.328	6.250	0.000
Year 1	Pooled	0.822	0.575	0.331	-0.304	1.949	1.430	0.153
Year 1	Prediction Interval							
Overall	Prediction Interval	0.756			-0.896	2.409		

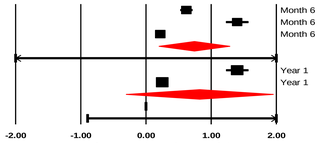


*Figure 3 Forest plot for the **mean change in CDVA** post-operatively compared to pre-operative values at 1m, 6m and 1 y.*

Group by Time point	Study name	Statistics for each study						
		Mean	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Month 1	Doroodgar (2017)	0.300	0.017	0.000	0.266	0.334	17.249	0.000
Month 1	Shaheen (2014)	-0.310	0.035	0.001	-0.379	-0.241	-8.790	0.000
Month 1	Pooled	-0.004	0.305	0.093	-0.602	0.594	-0.014	0.989
Month 1	Prediction Interval							
Month 6	Antonios (2015)	0.060	0.013	0.000	0.035	0.085	4.695	0.000
Month 6	Emerah (2019)	0.030	0.027	0.001	-0.022	0.082	1.122	0.262
Month 6	Hashemian (2018)	0.160	0.026	0.001	0.109	0.211	6.144	0.000
Month 6	Khalafallah (2023)	0.070	0.031	0.001	0.009	0.131	2.236	0.025
Month 6	Shaheen (2014)	-0.330	0.038	0.001	-0.405	-0.255	-8.574	0.000
Month 6	Pooled	0.001	0.060	0.004	-0.116	0.118	0.017	0.987
Month 6	Prediction Interval	0.001			-0.454	0.456		
Year 1	Antonios (2015)	0.060	0.013	0.000	0.035	0.085	4.695	0.000
Year 1	Doroodgar (2017)	0.320	0.021	0.000	0.278	0.362	15.043	0.000
Year 1	Hashemian (2018)	0.175	0.181	0.033	-0.180	0.530	0.966	0.334
Year 1	Khalafallah (2023)	0.060	0.030	0.001	0.001	0.119	1.984	0.047
Year 1	Shaheen (2014)	-0.330	0.038	0.001	-0.405	-0.255	-8.574	0.000
Year 1	Pooled	0.048	0.096	0.009	-0.140	0.236	0.497	0.619
Year 1	Prediction Interval	0.048			-0.667	0.763		
Overall	Prediction Interval	0.013			-0.392	0.419		

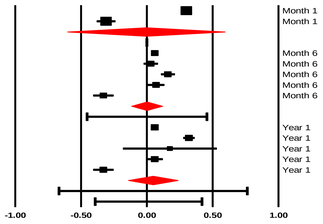
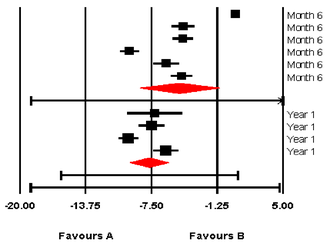


*Figure 4: Forest plot for the **mean change in SE** post-operatively compared to pre-operative values at 6m and 1 y.*

Group by Time point	Study name	Statistics for each study						
		Mean	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Month 6	Khalafallah (2023)	0.460	0.110	0.012	0.245	0.675	4.198	0.000
Month 6	Emerah (2019)	-4.500	0.556	0.309	-5.589	-3.411	-8.099	0.000
Month 6	Hashemian (2018)	-4.530	0.507	0.257	-5.523	-3.537	-8.937	0.000
Month 6	Kamiya (2015)	-9.590	0.457	0.209	-10.485	-8.695	-20.999	0.000
Month 6	Antonios (2015)	-6.100	0.609	0.371	-7.293	-4.907	-10.021	0.000
Month 6	Hashemian (2013)	-4.650	0.515	0.265	-5.659	-3.641	-9.029	0.000
Month 6	Pooled	-4.809	1.933	3.738	-8.599	-1.020	-2.487	0.013
Month 6	Prediction Interval	-4.809			-18.948	9.329		
Year 1	Khalafallah (2023)	-7.220	1.331	1.771	-9.829	-4.611	-5.425	0.000
Year 1	Doroodgar (2017)	-7.480	0.631	0.399	-8.718	-6.242	-11.846	0.000
Year 1	Kamiya (2015)	-9.690	0.464	0.215	-10.599	-8.781	-20.901	0.000
Year 1	Antonios (2015)	-6.130	0.614	0.377	-7.334	-4.926	-9.978	0.000
Year 1	Pooled	-7.691	0.939	0.883	-9.532	-5.850	-8.187	0.000
Year 1	Prediction Interval	-7.691			-16.094	0.712		
Overall	Prediction Interval	-7.141			-18.972	4.691		



Primary Outcomes:

- **Uncorrected distance visual acuity (UDVA):**At 6 months post-operatively, there was a statistically significant different change in UDVA compared to preoperative values, however at 1 year there was no statistically significant different change (*mean change*: 0.741, 95% CI: 0.199 to 1.283, P = 0.007; *mean change*: 0.822, 95% CI: -0.304 to 1.949, P =0.153, respectively).
- **Corrected distance visual acuity (CDVA):** At 1 month, 6 months, and 1 year post-operatively, there was no statistically significant change in CDVA compared to preoperative values (*mean change*: -0.004, 95% CI: -0.602 to 0.593, P = 0.989; *mean change*: 0.001, 95% CI: -0.116 to 0.118, P = 0.987; *mean change*: 0.048, 95% CI: -0.140 to 0.236, P = 0.619, respectively; figure 3).
- **Spherical equivalent (SE):** At 6 months and 1 year post-operatively, there was a statistically significant change in SE compared to pre-operative values (*mean change:* -4.809, 95% CI: -8.599 to -1.020, P = 0.013; *mean change:* -7.691, 95% CI: -9.532 to -5.850, P = 0.000, respectively; figure 4)

Secondary Outcomes:

- **Uncorrected close visual acuity (UCVA):** At 1 month, 6 months, and 1 year post-operatively there was a statistically significantly improvement in mean UCVA compared to pre-operative values (*mean* : 0.595, 95% CI: 0.134 to 1.056, P = 0.011; *mean*: 0.574, 95% CI: 0.379 – 0.889, P = 0.037; mean: 0.452 , 95% CI: 0.065 – 0.840, P = 0.022; respectively).
- **Astigmatism**: At 6-months post-operatively, there was a statistically significantly improvement in mean astigmatism compared to pre-operative values (*mean*: -0.582, 95% CI: -0.0793 to -0.372, P = 0.000).

CONCLUSION

- This single arm meta-analysis, incorporating 14 studies and 397 eyes, suggests that ICL use in eyes with stable keratoconus improves UDVA in the average eye by up to 7 lines (logMar mean difference 0.7) on the vision chart at 6 months post-operatively, however, the anlaysis did not detect a significant difference at 1 year . There was a reduction in spherical error and astigmatism.
- Limitations of this analysis are the limited number of studies available for meta-analysis of UDVA thereby decreasing the power of the analysis in addition to the relatively short time frame of included studies, reporting outcomes up to 12 months post-operatively.

REFERENCES

CONTACT INFORMATION

Ali Alkhabbaz, Ministry of Health, Kuwait
alkhabaz.97 @ gmail.com