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ORIGINAL ARTICLE

Comparative study of iris-claw intraocular lens implantation and implantable collamer lens

patient-reported outcomes

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Background

Iris-claw phakic intra-ocular lenses (pIOLs) and implantable collamer lenses (ICLs) are the main pIOLs in use. We aim to compare for the first time patient experience and satisfaction of these two techniques.

Methods

A cross-sectional study design, with no randomization or control groups was utilised. Patients who underwent either surgery between 2010 and 2020 were identified from hospital records. Phone interviews, performed in June 2021 used a semi-structured questionnaire divided into pre-operative build-up, patient experience and post-operative issues. A five-point Likert scale was used for standardisation. Perioperative data was collected from their medical files.

Results

After exclusions, 20 ICL patients (40 eyes) and 17 iris-claw patients (34 eyes) were included. A higher proportion of the ICL cohort completely agreed that the surgery has improved their vision significantly (ICL n=18, 90%; iris-claw n=8, 47%; P=.03) and that they would recommend it (ICL n=19, 95%; iris-claw n=8, 47%; P=.01). Postoperative issues were comparable, but iris-claw patients experienced more long-term glare (iris-claw n=8, 47%; ICL n=1, 5%; P<.01). Both techniques eliminated contact lens use. Astigmatic ICL patients were more satisfied, with 89%(n=17) completely agreeing that they would recommend the surgery, in comparison to 50%(n=6) of astigmatic iris-claw patients (P=.015).

Conclusion

ICL is superior to iris-claw in terms of patient satisfaction, efficacy and long-term issues, and also in astigmatic patients. Short-term issues were comparable. Both types of surgery succeeded in decreasing contact lens use, further contributing to an improved quality of life. Clinically this could help guide phakic intraocular lens technique selection for better patient satisfaction.

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Uncorrected refractive error is the second commonest cause worldwide of visual impairment after cataracts, with 43% of global visual impairment attributed it.[1] In a study published in 2015, over half of Europeans aged between 25 and 90 were estimated to have a refractive error, with the greatest burden being myopia.[2] Similar results were reported in the United States with half of individuals aged 20 or older having a clinically significant refractive error.[3] Uncorrected refractive error was also found to exert a significant economic impact, with the total productivity loss in international dollars estimated to be around a thousand times greater than the global number of cases.[4]

In phakic intraocular lens (pIOL) implantation a specially designed lens is inserted in front of the patient's own anatomical lens with the aim of correcting the ametropic error. pIOLs are mainly subdivided into three groups, based on their final position in the eye and fixation mechanism. Angle-supported anterior chamber pIOLs (ACIOLs) and iris-fixated ACIOLs lie anterior to the iris, whilst posterior chamber pIOLs (PCIOLs), such as implantable collamer lenses (ICLs), lie between the iris and the anatomical lens.[5] In practice, they are generally preferred as options for high-grade refractive error, with other refractive surgery techniques being used for lower degrees of ametropia. In fact, various studies have shown that pIOL implantation seems to be safer and a more effective in the treatment of moderate to high myopia in comparison to corneal-based refractive surgery, such as laser in situ keratomileusis (LASIK) and excimer laser refractive surgery.[6-8] It also seems to avoid the risks of retinal detachment and corneal ectasia, which are linked to refractive lens exchange and excimer laser surgery, respectively.[6] However caution and appropriate consideration is advised in patients with active anterior segment disease, cataracts, previous ocular surgery, glaucoma or raised intraocular pressure, pre-existing macular pathology, retinal disease, anomalous irises or pupils and systemic diseases associated with poor postoperative healing, such as diabetes mellitus.[5]

The main pIOL implantation techniques in use are the Verisyse (Artisan in Europe) iris-claw ACIOL and the Visian ICL, both of which are approved by the United States Food and Drug Administration (FDA) for correction of myopia with or without astigmatism of up to 2.5 Diopters (D).[5] A meta-analysis published in 2014 concluded that the refractive outcome of these two pIOLs was comparable, as was the safety. However while ICL implantation was found to have a better predictability, more complications were associated with it such as anterior subcapsular cataract.[9] On the other hand, Boxer Wachler et al reported that ICL had better refractive outcomes and binocular uncorrected visual acuity (UCVA) in comparison to iris-claw.[10] At our center, these are the main pIOL implantation techniques used. Patient selection for either pIOL surgery is based on published inclusion and exclusion criteria.[5] The only addition at our center is that patients who have a corneal thickness of less than 490µm are also considered for pIOL implantation in preference to corneal-based refractive surgery.

However to date there are no studies that compare the two widely-available pIOLs in terms of patient-reported outcomes. Through this study we aim to compare for the first time the experience of patients who underwent iris-claw pIOL implantation to that of patients who underwent ICL implantation, at our center. We aim to compare the effect the surgeries had on their lives, including post-operative short-term and long-term issues, and their degree of satisfaction.

MATERIALS AND METHODS

The study design chosen was a non-randomized cross-sectional study without a control group. Ethical approval was obtained from the University of Malta Faculty Research Ethics Committee on 4 June 2021. Patients who underwent iris-claw pIOL or ICL implantation at our center between May 2010 and May 2020 were identified from hospital records. To eliminate bias due to differing technique, only those operated on by Surgeon A, the only surgeon who used both surgical techniques, were included in the study. Due to the SARS-COV2 pandemic, data was collected via phone interviews in June 2021, ensuring at least one year of post-operative follow-up. Verbal informed consent was obtained prior to the interview. A semi-structured questionnaire subdivided into pre-operative build-up, patient experience, and post-operative issues was used. Patient experience was categorized and standardized through the use of a five-point Likert scale. Following the interviews, perioperative data was collected from their medical files, after obtaining consent. This included details about pre-operative refractive correction used, implanted lens power and position, corneal data, intra-operative details and any post-operative follow-ups. All of the data gathered was compiled in a secure database and analyzed using SPSS software.

RESULTS

PRE-OPERATIVE DATA

26 patients who underwent ICL implantation and 28 patients who underwent iris-claw pIOL implantation were eligible for the study. Due to patient preference or non-response to the participation invitation, some patients were excluded leaving a final number of 20 ICL implantation patients (40 eyes; 77%) and 17 iris-claw pIOL implantation patients (34 eyes; 61%). The age range of iris-claw patients was 22 to 52 years with an average age of 31.94 years, while the age range of ICL patients was 19 to 44 years with an average age of 33.55 years. No statistically significant difference was found in between the age of the two cohorts (Mann–Whitney U=133.5, n1=17, n2=20, P=.271 two-tailed).

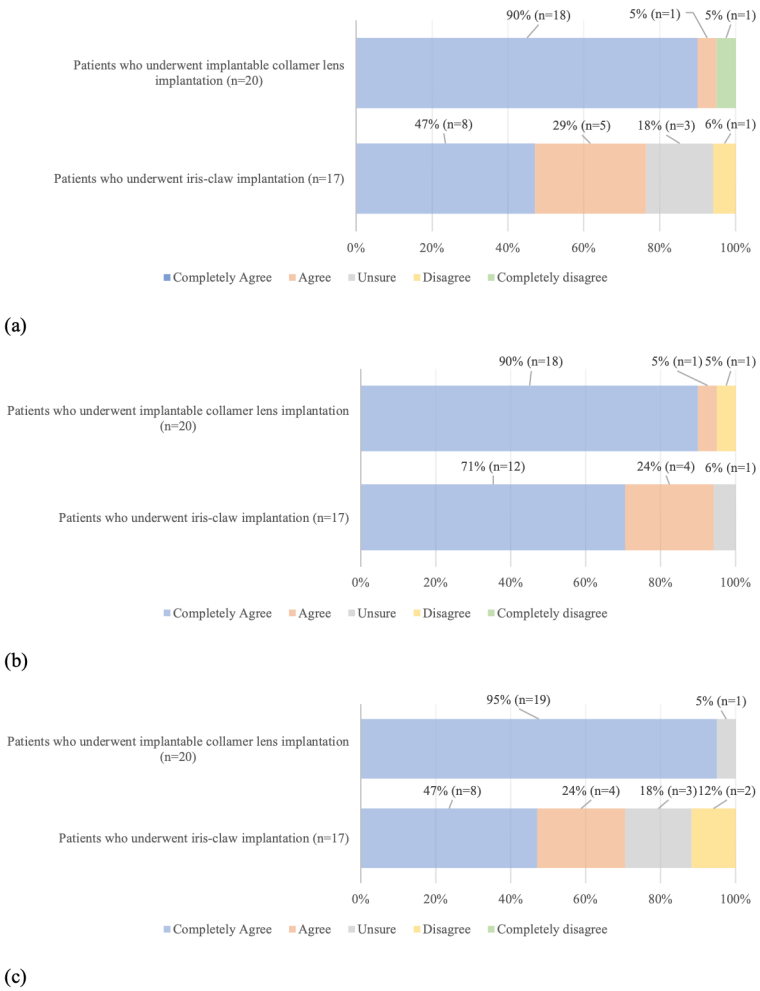

Figure 1 *Patient response to the following statements (a) 'The surgery has improved my vision significantly' (Mann–Whitney U=99.5, n1=17, n2=20, P=.03 two-tailed) (b) 'The surgery was a life-changing procedure' (Mann–Whitney U=139, n1=17, n2=20, P=.35 two-tailed) (c) 'I will definitely recommend this surgery to friends and family, if they require it' (Mann–Whitney U=89.5, n1=17, n2=20, P=.01 two-tailed)*

In negative cylinder notation, the refraction of the patients who underwent iris-claw implantation ranged from -4D to -18.5D of myopia and -0.5D to -4.5D of myopic astigmatism, per eye. On the other hand, those who underwent ICL implantation ranged from -3.5D to -16.25 of myopia and -0.5 to -4.5D of myopic astigmatism, per eye. Also the average subjective visual acuity in LogMAR was 0.11 (SD=0.15) for ICL patients and 0.26 (SD=0.12) for iris-claw patients. The average thinnest corneal thickness of iris-claw patients was 514.27µm (SD=36.45) compared to 533.63µm (SD=39.96) in ICL patients.

Pre-operatively iris-claw patients used predominantly a combination of glasses and soft contact lenses (CLs) (n=10, 59%), whilst the rest used glasses only (n=5, 29%) or a combination of glasses and hard CLs (n=2,12%). Similarly ICL patients used mainly a combination of glasses and soft CLs (n=17, 85%), followed by only soft CLs (n=2, 10%) or glasses only (n=1, 5%).

PATIENT SATISFACTION

To gauge patient satisfaction post-operatively, all patients were asked to rate their level of agreement with 3 statements in the form of a Likert scale. The statements were 'The surgery has improved my vision significantly', 'The surgery was a life-changing procedure', and 'I will definitely recommend this surgery to friends and family, if they require it'. The results are depicted in **Figure 1**.

POST-OPERATIVE RECOVERY AND ISSUES

Post-operatively 59% (n=10) of iris-claw patients did not require any further refractive correction, whilst 35% (n=6) required glasses and 6% (n=1) required further surgery and glasses, amounting to a total of 41% (n=7) who required further correction. On the other hand, 85% (n=17) of ICL patients did not require any further refractive correction, with the remaining 15% (n=3) requiring glasses (n=2, 10%) or further surgery (n=1, 5%) (P=.14, Fisher's exact test[FET]).

71% (n=12) of iris-claw patients reported an immediate satisfactory improvement of vision postoperatively, whilst 18% (n=3) said it took more than 1 day but less than 1 week, 6% (n=1) more than 1 week but less than 1 month, and a further 6% (n=1) more than one month. On the other hand, 95% (n=19) of ICL patients reported an immediate satisfactory improvement in vision post-operatively, with the remaining 5% (n=1) reporting that it took more than 1 day, but less than 1 week (Mann–Whitney U=127.5, n_1=17, n_2=20, P=.20 two-tailed).

The reported post-operative adverse events were subdivided into post-operative complications and post-operative issues to differentiate potentially preventable adverse events, termed 'complications', from non-preventable 'issues' that arise due to surgery. The post-operative issues were further subdivided into short-term issues lasting less than 6 months and long-term issues (unresolved issues or issues which lasted more than 6 months).

With regards to short-term post-operative issues, 76% (n=13) of iris-claw patients and 80% (n=16) of ICL patients reported that they had at least one (P>.99, FET). Between 1 and 4 issues were reported in 65% (n=11) of iris-claw patients and 75% (n=15) of ICL patients, with 12% (n=2) of iris-claw patients and 5% (n=1) of ICL patients reporting 5 or more issues. No short-term post-operative issues were reported in 24% (n=4) of iris-claw patients and 20% (n=4) of ICL patients. A further breakdown of the short-term issues along with their duration is provided in **Figure 2**. Fisher's exact test (FET) was used to calculate significance.

On the other hand, with regards to long-term post-operative issues, 65% (n=11) of iris-claw patients reported that they had between 1 and 4 issues. The remaining 35% (n=6) had no long-term issues. Meanwhile 40% (n=12) of ICL patients reported that they experienced between 1 to 4 issues, with the remaining 60% (n=8) claiming to have had no long-term issues (P>.99, FET). A further breakdown of the long-term issues is provided in **Figure 3**.

None of the iris-claw patients had any post-operative complications. However 2 ICL patients (10%) had a complication (P=.49, FET). One had post-operative torsion of the ICLs whilst the other had an absent vault between the left ICL and the anterior capsule, requiring explanation of both ICLs.

ASTIGMATISM AND PIOL IMPLANTATION

82% (n=14) of the iris-claw cohort and 90% (n=18) of the ICL cohort were astigmatic. 21% (n=3) of astigmatic iris-claw patients and 94% (n=17) of the astigmatic ICL cohort were corrected with a toric pIOL (P<.001, FET). An analysis of the astigmatic patients' responses is provided in **Figure 4**.

DISCUSSION

All of our study participants had some sort of refractive correction pre-operatively showing that they all deemed their uncorrected vision to be insufficient for daily life. The main aim of refractive surgery and hence pIOL surgery is to change the

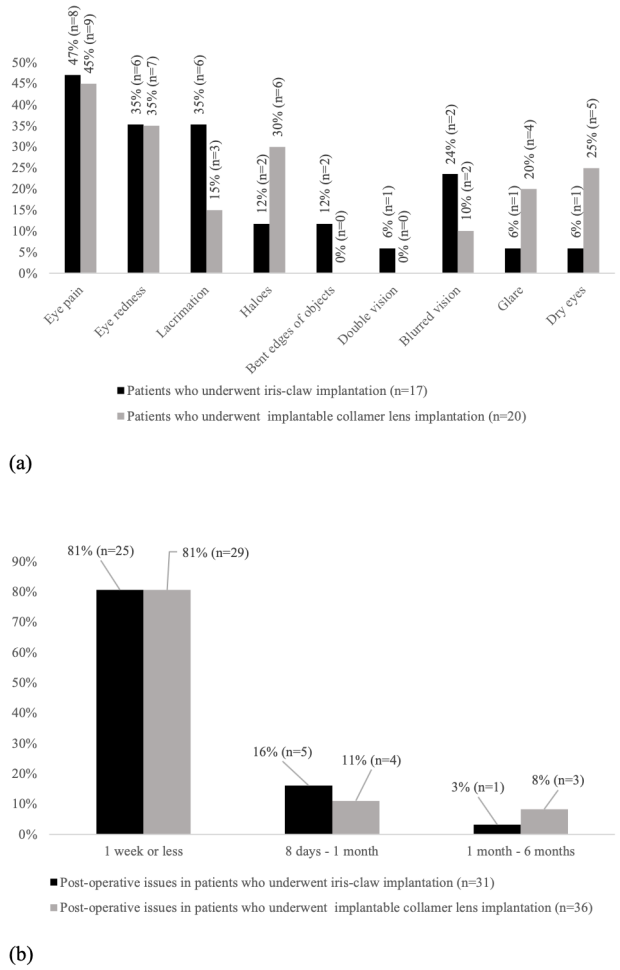

Figure 2 *a) Commonest short-term post-operative issues (occurred in first 6 months and are now resolved) reported by the 2 patient cohorts [eye pain: P>.99; eye redness: P>.99; lacrimation: P=.25; haloes: P>.99; bent edges: P=.20; double vision: P=.46; blurred vision: P=.38; glare: P=.35; dry eye: P=.19] (b) Duration of the short-term post-operative issues (Mann–Whitney U=552, n1=31, n2=36, P=.94 two-tailed)*

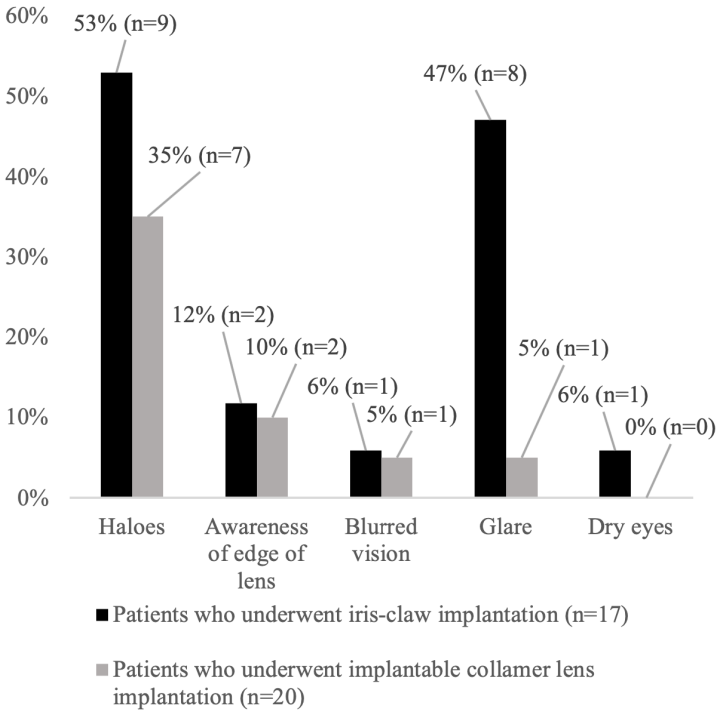

Figure 3 *a)Commonest long-term post-operative issues (still unresolved) reported by the 2 patient cohorts [haloes: P=.33; awareness of lens edge: P>.99; blurred vision: P>.99; glare: P=.006; dry eye: P=.46]*

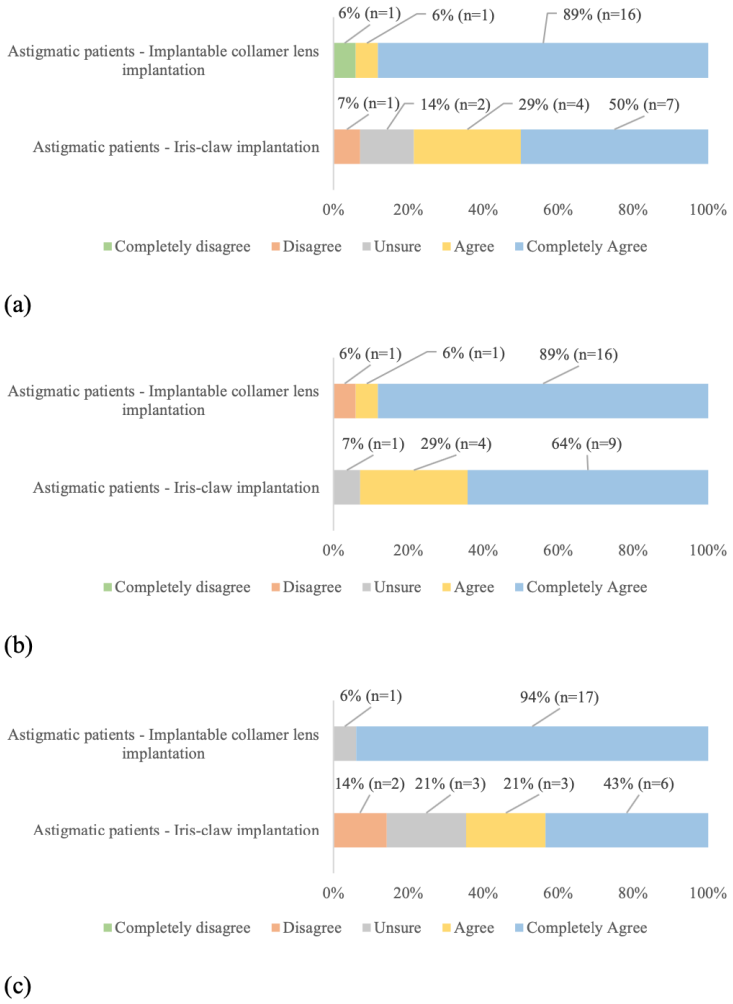

Figure 4 *Comparison of astigmatic patient response to the following statements (a) 'The surgery has improved my vision significantly' (Mann–Whitney U=82, n1=14, n2=18, P=.099 two-tailed) (b) 'The surgery was a life-changing procedure' (Mann–Whitney U=99.5, n1=14, n2=18, P=.32 two-tailed) (c) 'I will definitely recommend this surgery to friends and family, if they require it' (Mann–Whitney U=61.5 n1=14, n2=18, P=.015 two-tailed)*

A lot of published studies compare these two surgical techniques objectively, but our study is the first to compare them in terms of patient-reported outcomes. When asked whether the surgery has improved their vision significantly, 85% of ICL patients compared to 47% of the iris-claw cohort completely agreed. This shows that a significant improvement in vision post-operatively was noted in a statistically significant (P=.03) higher proportion of the ICL cohort. Furthermore with respect to whether they would recommend the surgery to friends and family, a higher proportion of ICL patients (90%) completely agreed in comparison to iris-claw patients (59%), with this difference being statistically significant (P=.01). Similar to these results, the surgery was also deemed to be life-changing by a higher proportion of ICL patients (90% ICL versus 71% iris-claw). However this was not statistically significant (P=.35).

From the responses obtained to these statements, ICL implantation resulted in higher patient satisfaction in comparison to iris-claw implantation, with the results for two out of the three statements found to be statistically significant.

In our study, post-operative adverse events were subdivided into post-operative complications and post-operative issues, to differentiate potentially preventable adverse events, termed complications, from non-preventable issues that arise due to surgery. In the iris-claw cohort, no significant complications were reported. On the other hand, in the ICL cohort 2 patients (10%) had a significant documented complication, one of which required explantation of the ICLs. Patient A, who had bilateral toric ICLs implanted, presented 2 months post-operatively with a rotated right toric ICL, which was followed by torsion of the left toric ICL 4 months later. The patient was subsequently offered femto-LASIK, but opted to use glasses instead. On the other hand, patient B had to have the ICLs explanted 1 week post-operatively due to the absence of a vault in between the left ICL and the anterior capsule. Patient B's myopia was subsequently treated with the small excision lenticule extraction (SMILE) procedure.

Unsurprisingly Patient B completely disagreed with the first statement, disagreed with the second statement, and was unsure whether they would recommend the surgery to friends and family. Interestingly however, Patient A completely agreed with all 3 statements, even though both ICLs rotated post-operatively. This could further show that whilst the objective result was different to the planned end-point, the patient still perceived a significant change in visual acuity and was satisfied to use low-powered glasses as an adjunct to the ICLs.

Post-operative issues were further subdivided into short-term and long-term issues. No statistically significant difference was found between the short-term and long-term issue rates in both cohorts (P>.99), however the iris-claw cohort reported a higher prevalence of long-term glare when compared to the ICL cohort (P=.006), raising the possibility that differences in lens design could have contributed to this.

The commonest long-term issues in iris-claw patients were haloes (53%), glare (47%) and awareness of the edge of the lens (12%). In the ICL cohort, haloes were also the commonest long-term issue (35%), followed by awareness of the edge of the lens (11%), blurred vision (5%) and glare (5%). This follows that while both cohorts had similar long-term effects, these occurred at a lower frequency in the ICL cohort. With regards to short-term issues, the commonest

reported in either cohort were similar. Eye pain (47%), eye redness (35%), increased lacrimation (35%) and blurred vision (24%) were the commonest in the iris-claw cohort, whilst eye pain (45%), eye redness (35%), haloes (30%) and dry eyes (25%) were the commonest reported in the ICL cohort. With regards to duration, the majority of short-term issues lasted 1 week or less in both cohorts (81% in both cohorts), whilst all issues which lasted more than 6 months were still unresolved.

Another lower-order aberration that needs to be taken into consideration is astigmatism. In our study, a comparable proportion of iris-claw patients (82%), and ICL patients (90%) were astigmatic. However much less astigmatic iris-claw patients (21%) were implanted with a toric pIOL in comparison to ICL astigmatic patients (94%), due to the technical difficulties in alignment and lack of surgeon experience with toric iris-claw implantation. This difference was found to be statistically significant (p<.001) and therefore limits the amount of comparisons that can be made between the two astigmatic cohorts.

With regards to the astigmatic patients' satisfaction postoperatively, 83% of astigmatic ICL patients completely agreed, in comparison to 50% of astigmatic iris-claw patients, that the surgery had improved their vision significantly (P=.099). With respect to whether the surgery was a life changing procedure, 89% of the astigmatic ICL cohort and 64% of the astigmatic iris-claw cohort completely agreed (P=.32). Finally 89% of the ICL astigmatic cohort completely agreed that they would recommend the surgery to friends and family, whilst only 50% of astigmatic iris-claw patients completely agreed with this (P=.015). This shows that a generally higher satisfaction was reported by the astigmatic ICL cohort. However a statistically significant difference between the responses was only found in the last statement.

Finally both of the significant complications mentioned above occurred with toric ICLs. Published studies indicate that toric ICLs have good rotational post-operative stability.[15,16] In one study, 90% of toric lenses were found to have rotated less than 5 degrees between all visit intervals.[16] In our study, of the 40 eyes implanted with toric ICLs only 2 (5%) suffered from clinically-significant rotation, whilst 94% did not. Although our results seem to concur with the published results, the degree of rotation was not measured, limiting further inferences.

Our study has a number of limitations. The SARS-COV2 pandemic national restrictions and patient preference made in-person patient interviews and examination difficult to organize. This would have allowed an objective comparison to be carried out alongside the subjective comparison of the two pIOL surgeries. Secondly even though all patients who underwent pIOL surgery at our center were included, the small sample size limits further conclusions. Finally only a small number of astigmatic patients

SUMMARY BOX

What is already known about this subject

- Uncorrected refractive error is the second commonest cause worldwide of visual impairment after cataracts, with 43% of global visual impairment attributed it.
- In phakic intraocular lens implantation a specially designed lens is inserted in front of the patient's own anatomical lens with the aim of correcting the refractive error.
- Various studies have shown that pIOL implantation seems to be safer and a more effective in the treatment of moderate to high myopia in comparison to corneal-based refractive surgery, such as laser in situ keratomileusis and excimer laser refractive surgery.
- The main phakic intraocular lens implantation techniques in use are the Verisyse (Artisan in Europe) iris-claw ACIOL and the Visian implantable collamer lens. A meta-analysis published in 2014 concluded that the refractive outcome of these two pIOLs was comparable, as was the safety. However to date there are no studies that compare the two widely-available pIOLs in terms of patient-reported outcomes.

What are the new findings

- Implantable collamer lens implantation is superior to iris-claw implantation in terms of patient satisfaction and post-operative need for refractive correction. It is also superior in astigmatic patients, but a larger cohort is required for statistical significance.
- Short-term issues were comparable between the two cohorts, but Implantable collamer lens patients reported a statistically significant lower incidence of long-term glare.
- Both types of phakic intraocular lens implantation surgery succeeded in decreasing contact lens use, potentially further contributing to an improved quality of life.

were implanted with a toric iris-claw which constricts direct comparison with toric ICLs and major inferences about the astigmatic cohorts.

In conclusion, ICL implantation was found to be superior to iris-claw implantation in terms of patient satisfaction, efficacy and long-term issues. It resulted in higher patient satisfaction, with a larger proportion of ICL patients reporting an immediate satisfactory improvement in vision and a lower need for further refractive correction post-operatively. Short-term issues were comparable between the two cohorts, but ICL patients reported a lower incidence of long-term glare. Both types of pIOL surgery succeeded in decreasing contact lens use, potentially further contributing to an improved quality of life. Finally a higher rate of patient satisfaction was reported with ICL implantation the astigmatic cohort, but larger studies are needed to confirm this. A comparison of the two pIOL implantation techniques with larger patient cohorts, potentially in a collaboration between different centers, could further consolidate this study's findings and help improve patient satisfaction post-pIOL surgery.

ACKNOWLEDGEMENTS

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ABBREVIATIONS

ACIOL	Anterior chamber intraocular lens
D	Diopters
FDA	Food and Drug Administration
ICL	Implantable collamer lens
PCIOL	Posterior chamber intraocular lens
pIOL	Phakic intraocular lens
SARS-COV2	Severe acute respiratory syndrome coronavirus 2
SD	Standard deviation

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