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A Systematic Review on Three Major Types of Scleral-Fixated Intraocular Lens Implantation

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A Systematic Review on Three Major Types of Scleral-Fixated Intraocular Lens Implantation

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Purpose: We performed a systematic review on 3 major types of scleral-fixated intraocular lens (SFIOL) implantations and conducted subgroup analyses on pediatric population and subjects with Marfan syndrome.

Design: Systematic review.

Methods: We performed a search in PubMed, Ovid MEDLINE, and Embase for English language articles with keywords "(sutured intraocular lens) OR (SFIOL) OR (sutureless intraocular lens) OR (glued intraocular lens) OR (intrascleral intraocular lens) OR (SFIOL)" through October 16, 2019. Articles reporting individual outcomes after SFIOL were included in this systematic review. Recorded outcome measures included intra-operative and postoperative complications, endothelial cell changes, and intraocular lens-related outcomes.

Results: Our search yielded 217 papers. After removing duplicated and irrelevant reports, we included 57 articles involving 2624 eyes. The mean age at operation was 51.47 ± 25.62 years. Sutured SFIOL was most commonly reported in all subjects with Marfan syndrome and 92.87% of pediatric patients. The pooled intraoperative complication rate was 6.65%. Minor anterior chamber hemorrhage was the most common intraoperative (1.92%) and postoperative complication (13.93%). Optic capture was the top intraocular lens (IOL)-related complication (4.47%). The overall mean endothelial cell loss was 8.95% at 16.77 ± 11.04 months. Overall 11.99% of SFIOLs were decentred with a mean distance of 0.49 ± 0.40 mm and a mean degree of tilt by $4.11 \pm 3.03^{\circ}$.

Conclusions: Glued SFIOL had the fewest IOL-related complications and the lowest endothelial cell loss. Sutured SFIOL carried the highest IOL-related complications, whereas sutureless, glueless SFIOL was associated with the greatest endothelial cell loss.

Key Words: aphakia, cataract, cornea, intraocular lens, scleral-fixation

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Cataract is the global leading cause of blindness and cataract surgery with the implantation of intraocular lens (IOL) is the most commonly performed elective ophthalmic operation worldwide.[1] After removal of the cataract, an IOL is usually implanted within the capsular bag. However, endocapsular implantation of IOL is not always feasible, due to the inadequate zonular and/or capsular support. In these situations, the surgeon needs to consider alternatives including leaving the eye aphakic, placing an anterior chamber IOL or IOL fixation either to the iris or sclera.[2,3] In recent years, variations of scleral-fixated IOL (SFIOL) using tissue adhesive glue or sutureless, glueless approach were proposed. Although these approaches may seem to be simpler than conventional suture techniques, the safety and outcome such as the effects on endothelial cells and IOL tilting had not been systematically reviewed.

We set out to conduct a systematic analysis on 3 major types of SFIOL, namely sutured SFIOL (SSFIOL), glued SFIOL (GSFIOL), and sutureless, glueless SFIOL, and evaluate the intraoperative and postoperative complications, endothelial cell changes, and postoperative IOL positions.

MATERIALS AND METHODS

Search Strategy

We searched PubMed, Ovid MEDLINE, and Embase for studies evaluating the different kinds of SFIOL. In the above databases, we adopted the following strategy "(sutured IOL) OR (SFIOL) OR (sutureless IOL) OR (GSFIOL) OR (intrascleral IOL) OR (SFIOL)" without limitation on the time of publication. The language was restricted to English in our search. Our search yielded 1399, 108, and 206 titles from PubMed, Ovid MEDLINE, and EMBASE, respectively. We performed the final search on October 16, 2019.

Inclusion and Exclusion Criteria

Two reviewers (H.M.W. and K.W.K.) independently assessed the titles to identify articles that fulfilled the inclusion criteria: (1) clinical studies/clinical trials/comparative studies/randomized controlled trials; (2) studies that included human subject(s); and (3) studies that assessed SFIOL at the time of cataract or lens surgery or as a secondary procedure. Any discrepancies were resolved by discussion amongst the reviewers. We excluded studies that only discussed iris-fixated IOL or sulcus-fixated IOL, or any types of IOL without comparison to SFIOL, or studies that did not provide sufficient data for analysis. We also excluded studies on SFIOL at the time of corneal transplantation as the latter procedure carries additional risks and complications. We also reviewed the references of articles to identify any relevant studies that were not identified in the initial literature search.

Data Extraction

Duplicated data of identical patients reported in more than 1 article were eliminated. We customized a data collection form to record the following details: authorship, year of publication, country of publication, sample size, mean age of subjects, type of SFIOL, and preoperative best-corrected visual acuity (BCVA). Snellen visual acuity was converted to LogMAR (Logarithm of Minimal Angle of Resolution) units. Counting finger and hand movement were equivalent to 2.0 and 3.0 LogMAR units, respectively. Visual acuity of light perception or less was excluded from calculation of the geometric mean. Studies that only reported the median value or range of visual function were excluded from the analysis. Information regarding the perioperative complications, postoperative visual acuity, changes in the density of endothelial cell, and IOL-related complications specifically on decentration and tilting were extracted. Unclear or insufficient data were discarded from statistical analyses where appropriate.

Statistical Analysis

After a detailed assessment of data from all the included studies, we found no single parameter eligible for meta-analysis. Therefore, in this systematic review, we reported the mean and standard deviation, and percentage of incidence for descriptive statistics where appropriate.

RESULTS

We identified a total of 217 studies in the 3 databases fulfilling our inclusion criteria. After removing 15 duplicates, we assessed 202 titles and abstracts and excluded 138 records that were not eligible for data extraction. We then retrieved 64 articles for full-text review but 7 were excluded as no full text was available. We finally included 57 studies into the systematic review. Figure 1 is the flowchart of our study inclusion.

Characteristics of the Included Studies

The 57 included studies involved a total of 2624 eyes. These studies were published between 1992 and 2019. Among them, 44 (77.19%) studies were conducted in Asian populations from India (n = 14), Turkey (n = 8), Korea (n = 6), followed by Hong Kong (n = 5), Japan (n = 5), China (n = 3), Egypt (n = 2), and Nepal (n = 1). The remaining 13 studies were conducted in North America (n = 6), Europe (n = 6), and Australia (n = 1). We identified 22 case series and 35 comparative studies. There was no level I evidence identified from our literature search.

Among these studies, 3 major types of scleral-fixation techniques were covered. There were 42, 9, and 12 reported studies on SSFIOL, GSFIOL, and sutureless, glueless technique, involving 1935, 226, and 463 eyes, respectively.

Demographics

Table 1 is a summary of the demographic data of the included 2624 eyes. The mean age at the time of surgery, reported in 2040 eyes, was 51.47 ± 25.62 years. Of all the eyes with reported visual function, the mean preoperative BCVA was 0.89 ± 0.78 (~Snellen 20/155) and postoperative BCVA was 0.41 ± 0.50 (~Snellen 20/50).

Complications of SFIOL

Overall Intraoperative Complications

Intraoperative complications were reported in 20 studies consisting of 677 eyes.[4–23] Table 2 is a summary of all 45 reported intraoperative complications. The overall intraoperative complication rate was 6.65%. The most common intraoperative complication was minor hemorrhage involving 13 eyes (1.92%), followed by vitreous prolapse in 9 eyes (1.33%). Seventeen complications involved the IOL haptics, including haptic kink (n = 7, 1.03%), haptic breakage/damage (n = 7, 1.03%), haptic slippage (n = 2, 0.30%), and insufficient haptic to tuck (n = 1, 0.15%). Among these 677 eyes, 1 eye experienced intraoperative IOL drop as a serious complication (0.15%) with no further details given.[12] None of the studies that reported intraoperative

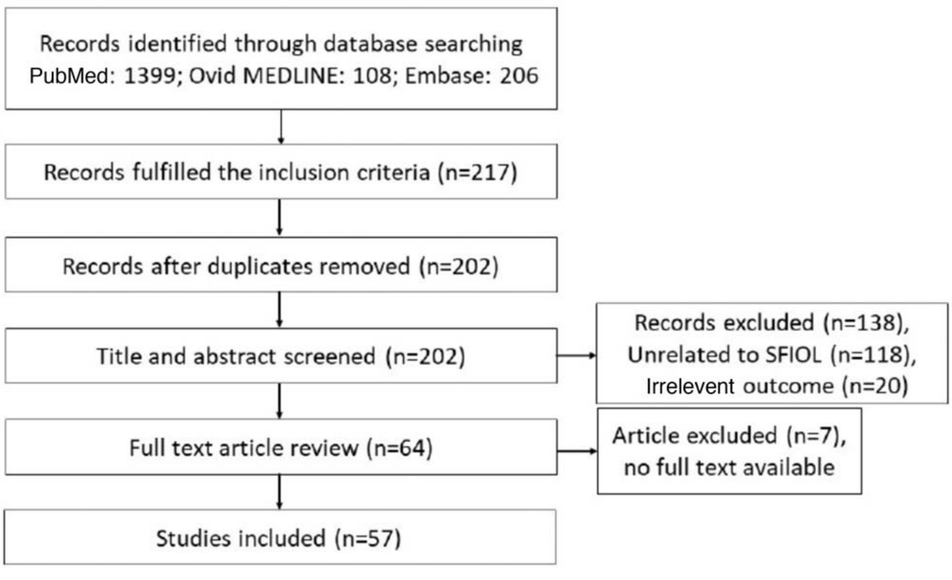

FIGURE 1. Flowchart of study selection and inclusion process.

TABLE 1. Demographic and Preoperative and Postoperative Visual Acuity Among the Included Studies

	No. Studies	No. Eyes	Age, Mean ± SD	Preoperative Best-Corrected Visual Acuity (LogMAR), Mean ± SD	Postoperative Best-Corrected Visual Acuity (LogMAR), Mean ± SD
Overall	57	2624	51.47 ± 25.62	0.89 ± 0.78	0.41 ± 0.49
Sutured SFIOL	42	1935	49.55 ± 27.32	0.99 ± 0.76	0.46 ± 0.52
Glued SFIOL	9	226	50.02 ± 18.35	0.85 ± 0.80	0.21 ± 0.39
Sutureless, glueless SFIOL	12	463	59.23 ± 19.80	0.67 ± 0.78	0.33 ± 0.42
SFIOL in pediatric and young adult population	9	421	9.90 ± 4.85	1.16 ± 0.89	0.49 ± 0.60

SD indicates standard deviation; SFIOL, scleral-fixated intraocular lens.

complications had mentioned IOL tilting as a postoperative complication.

Overall Postoperative Complications

Forty-eight studies reported postoperative summarized summarised in Table 3.[4–14,16–52] The incidence rate of a particular complication was reported as the fraction of eyes experiencing the complication out of the total number of eyes in all studies reporting this complication.

The most common postoperative complications were elevated intraocular pressure (14.04%) followed by anterior chamber hyphema (13.93%) and corneal edema (12.85%). Major postoperative complications such as retinal detachment (2.22%), choroidal detachment (2.50%), and endophthalmitis (0.27%) were rare. Other vision-threatening complications such as glaucoma (8.37%), macular edema (6.25%), vitreous hemorrhage (5.49%), and IOL subluxation/dislocation (2.86%) were occasionally reported.

Endothelial Cell Loss

The mean preoperative or postoperative, or mean percentage changes in corneal endothelial cell density were reported in 12 studies, that 6 were SSFIOL,[7,25,29,32,47,53] 4 were GSFIOL,[5,28,47,54] and 3 were sutureless, glueless SFIOL.[20,22,52] Kwong et al[32] reported only the postoperative specular endothelial cell count and was excluded from the analysis. Only 1 study reported a stable endothelial cell count with SSFIOL postoperatively using either intrascleral pocket or scleral flap techniques.[53] All other 10 studies reported a postoperative loss of corneal endothelial cells. Among the 11 studies with sufficient data on endothelial cell changes, the mean endothelial cell loss was 8.95% at a mean follow-up period of 16.77 ± 11.04 months. Table 4 is a summary of the details on endothelial cell density.

TABLE 2. Summary of Reported Intraoperative Complications During SFIOL implantation

Intraoperative Complications	No. Cases, n (%)
Minor hemorrhage	13 (1.92)
Vitreous prolapse	9 (1.33)
Hyphema	4 (0.59)
Haptic kink	7 (1.03)
Haptic breakage/damage	7 (1.03)
Haptic slippage	2 (0.30)
Insufficient haptic to tuck	1 (0.15)
IOL drop	1 (0.15)
Sommering ring drop	1 (0.15)
Total	45 (6.65)

IOL indicates intraocular lens; SFIOL, scleral-fixated intraocular lens.

IOL-Related Complications

The most common IOL-related complication was optic capture. Forty-two accounts (4.47%) were reported in 17 studies from 940 eyes.[8,9,11,20,22,23,25,27,28,31,32,35,36,42,43,49,52] Thirty-nine IOL subluxations/dislocation (2.86%) were reported by 16 studies among 1365 eyes [5,9,10,22,24,25,29,31,33,35,38,42,44,50–52] and IOL haptic exposure occurred in 5 of 201 eyes among 6 studies (2.49%; see Table 3).[6,17,18,20,33,39]

IOL position was reported to be centered in 185 eyes (80.79%) among 11 studies with 229 eyes.[5,14,19,34,35,37,43,48,50,55,56] Decentration of IOL was reported in 96 eyes (11.99%) in 23 studies including 801 eyes.[4,5,7,9,13–15,25,26,28,30–32,34–36,41,45,46,49,55–57] Among all the studies reporting postoperative IOL decentration, only 1 reported the visual outcome (of BCVA 20/25) in an eye with IOL decentration.[28] Four eyes required secondary surgical operations (4.17%).[41,45,55] However, these studies did not report the visual acuities before and after the secondary procedures. The magnitude of decentration was quantified in millimeters (mm) by 4 studies[20,39,55,57] including 171 eyes and measured by different methods including Pentacam® Tomographer,[39] Scheimpflug videokeratophotography system,[57] Purkinje images,[55] and ultrasound biomicroscopy.[20] The mean decentration in these 4 studies was 0.49 ± 0.40 mm, and ranged from 0.15 to 0.62 mm.

Nineteen studies, including 771 eyes, reported 70 cases of clinically significant IOL tilting (9.08%)[4,14,19,23,25,27,34,35,37,43,47,48,51,55–59] as defined by IOL tilting of more than 5°.[47] Six other studies quantified the degree of IOL tilting[20,39,47,52,55,57] with methods mentioned above and 1 additional study utilized ultrasound biomicroscopy to measure the position of IOL[47] and anterior segment optical coherence tomography.[52] The mean degree of tilting was $4.11 \pm 3.03°$ (see Table 5). There was no report of secondary complications such as persistent inflammation in any eye with significant IOL tilting.

Sutured SFIOL

SSFIOL was the first technique described and this review included 42 studies on its clinical usage, outcome, and complications.[4,6–10,13–16,19,21,23–25,27,29–34,36–39,41–44,46,47,49–51,53,55–60]

Surgical Sutures and Sclerotomy Locations for IOL Fixation

Of the 42 included studies, 3 did not report on the type of suture used.[24,36,37] One study reported using 8–0 polypropylene suture,[50] 2 studies were on 9–0 polypropylene suture,[47,49] 1 study employed Gore-Tex® CV-8 suture,[23] and the remaining 35 studies were on 10–0 polypropylene for SSFIOL. Eighteen of the 35 studies that used 10–0 polypropylene suture for SSFIOL were published in 2010 or earlier, whereas only 1 of 4 studies that

TABLE 3. Summary of Postoperative Complications

Postoperative Complications	No. Studies Reported, n	Total No. Eyes Included, n	No. Cases, n (%)
Fibrin in anterior chamber	6	261	19 (7.28)
Anterior chamber hyphema	15	323	45 (13.93)
Uveitis-glaucoma-hyphema syndrome	2	136	1 (0.74)
Corneal edema	18	856	110 (12.85)
Bullous keratopathy/corneal decompensation	10	602	19 (3.16)
Macular edema	29	1584	99 (6.25)
Cellophane maculopathy/macular pucker/epiretinal membrane	7	215	14 (6.51)
Choroidal detachment	5	561	14 (2.50)
Retinal break	2	130	1 (0.77)
Retinal detachment	30	1751	39 (2.22)
Endophthalmitis	20	1117	3 (0.27)
Vitreous hemorrhage	24	1439	79 (5.49)
Vitreous prolapse into anterior chamber/wound	11	416	20 (4.81)
IOL optic capture	17	940	42 (4.47)
IOL subluxation/dislocation	19	1365	39 (2.86)
IOL haptic exposure	6	201	5 (2.49)
Suture extrusions/exposure	16	977	35 (3.58)
Suture breakage	4	279	0 (0.00)
Wound leakage	2	135	3 (2.22)
Elevated intraocular pressure/ocular hypertension	29	1645	231 (14.04)
Glaucoma	14	665	44 (6.62)
Hypotony	10	577	26 (4.51)

IOL indicates intraocular lens.

used non-10–0 polypropylene sutures was published earlier than 2010.

Regarding the location of sclerotomies for suture fixation in relation to the surgical limbus, 28 studies indicated a location at 0.8–1.5 mm,[4,6–8,10,14–16,19,21,25,29–34,37,38,42,43,46,49,53,55–57,59] other reported locations included 0.5,[44] 0.75,[4,58] 2,[13,23,47,51] 2.5,[50] and 3 mm [9,25] post-limbus, whereas 7 studies did not specify the sclerotomy locations.[9,24,27,36,41,56,60] Among the 279 pediatric

TABLE 4. Mean Specular Endothelial Cell Counts and Mean Percentage Change After SFIOL

Author	Type of SFIOL	No. Eyes, n	Mean Preoperative Specular Count (cell/mm^2)	Mean Postoperative Specular Count (cell/mm^2)	Mean Percentage Changes (mean%)	Mean Follow-Up (Months ± SD)
Kim et al[29]	SSFIOL	44	NA	NA	−10.9	16.6 ± 6.6
Cho et al[53]	SSFIOL Intrascleral pocket group	20	2010 ± 53	2013 ± 73	+0.15	NA
Cho et al[53]	SSFIOL Conventional-flap group	20	2045 ± 62	2056 ± 51	+0.535	NA
Zheng et al[7]	SSFIOL	39	2830.4 ± 641.9	NA	−19.5	12.0
Kwong et al[32]	SSFIOL	36	NA	1695 ± 695	NA	32.8 ± 18.2
Sinha et al[47]	SSFIOL	20	2177.55 ± 419	NA	−11.5	NA
Ma et al[25]	SSFIOL ciliary sulcus	38	2012.84 ± 875.21	1792.84 ± 119.34	−10.9	42.33 ± 22.90
Ma et al[25]	SSFIOL pars plana	56	1833.51 ± 989.80	1739.39 ± 952.98	−5.14	19.13 ± 12.28
	SSFIOL	273			+0.535 to −19.5	
Narang et al[5]	Glued SFIOL	19	2432.6 ± 336.1	2296.4 ± 301.1	−5.1	8.9 ± 2.1
Prakash et al[54]	Glued SFIOL	3	1713.3 ± 151.6	1453.3 ± 216.99	−15.2	6.0
Oh et al[28]	Glued SFIOL IOL reposition	13	2275 ± 693	2159 ± 615	−5.09	NA
Oh et al[28]	Glued SFIOL IOL exchange	12	2426 ± 353	2282 ± 344	−5.93	NA
Sinha et al[47]	Glued SFIOL	20	2239.05 ± 537	NA	−8.95	NA
	Glued SFIOL	67			−5.1 to -8.95	
Yamane et al[52]	Sutureless glueless SFIOL	100	2341 ± 481	2244 ± 282	−4.14	20.6 ± 10.0
Shuaib et al[20]	Sutureless glueless SFIOL	15	3208.3 ± 571.2	2739.9 ± 542.9	−14.6	6.0
Kelkar et al[22]	Sutureless glueless SFIOL modified Gabor technique	30	2342.75 ± 405.75	2009.32 ± 752	−14.2	11.5 ± 2.3
Kelkar et al[22]	Sutureless glueless SFIOL modified Yamane technique	40	2429.42 ± 465.50	2120.20 ± 843	−12.7	8.6 ± 1.9
	Sutureless glueless SFIOL	185			−4.14 to −14.6	
Overall					**−8.95**	**16.77 ± 11.04**

IOL indicates intraocular lens; NA, not applicable; SD, standard deviation; SFIOL, scleral-fixated intraocular lens; SSFIOL, sutured scleral-fixated intraocular lens.

TABLE 5. Postoperative IOL Position, Tilting, and Decentration

IOL Position	No. Studies Reported	No. Patients Included	Results
IOL centered, n (%)	10	220	176 (80.00%)
IOL decentration, n (%)	23	801	96 (11.99%)
IOL decentration length in mm, (mean ± SD)	4	171	0.49 ± 0.40
IOL significant tilting clinically, n (%)	17	658	69 (10.49%)
IOL tilting in degrees (mean ± SD)	5	211	4.45 ± 3.20

IOL indicates intraocular lens; SD, standard deviation.

patients for whom a 0.5-mm postlimbus for sclerotomies was used, there were 8 cases of postoperative dispersed vitreous hemorrhage (2.86%).[44]

Outcomes and Complications of SSFIOL

Our review analyzed 1935 eyes with SSFIOL, the mean age of the patients was 49.55 ± 27.32 years. The mean visual acuity improved from 0.99 ± 0.76 preoperatively to 0.46 ± 0.52 postoperatively. There was a total of 216 IOL-related complications (11.16%). The most common IOL-related complication was IOL decentration (n = 91 eyes, 4.70%),[7,9,13,14,25,30–32,36,41,49,55–57] followed by tilting of IOL (n = 68, 3.51%).[25,27,51,55,57] Other IOL-related complications included 21 IOL optic capture (1.09%) [8,9,16,27,31,32,42,43,49] and 36 IOL subluxations/dislocations (1.86%).[9,10,24,25,29,33,44,51] In terms of IOL decentration, 3 studies measured the IOL decentration and IOL tilting by Scheimpflug videokeratophotography[39,57] and Purkinje images,[55] the mean IOL decentration was 0.55 ± 0.39 mm from the optic center and the mean degree of tilting was 5.57 ± 3.39°. The mean endothelial cell loss was 8.18% at a mean follow-up period of 24.57 ± 11.26 months.[7,25,29,47,53] In terms of sutures in SSFIOL, there were 34 suture-related complications (1.76%), all of which were postoperative suture extrusions through the scleral flap or conjunctiva.[6,8,16,24,25,31,38,41,42,47,49,51] None of the studies reported suture breakage at a mean follow-up of 21.47 months.

Glued SFIOL

GSFIOL is a technique described in 2008 in cases with posterior capsule dehiscence.[61] In this systematic review, only 9 studies reported the outcome and complications of glued SFIOL.[5,6,11,12,26,28,35,47,54]

Outcomes and Complications of Glued SFIOL

The mean age of patients for the 226 GSFIOL eyes was 50.02 ± 18.35 years. The mean preoperative BCVA was 0.85 ± 0.80 and the mean postoperative BCVA was 0.21 ± 0.39. There were a total of 7 IOL related complications (3.10%) namely 3 IOL decentrations (1.33%),[26,28] 3 IOL optic capture (1.33%) [26,28] and 1 haptic exposure/erosion (0.44%).[6] The mean endothelial cell loss was 8.05% at a mean follow-up period of 7.45 ± 1.45 months.[12,28,47,54] There was no report of clinically significant IOL tilting; however, Sinha et al[47] reported 1.78 ± 0.97° of IOL tilting as measured by ultrasound biomicroscopy, whereas Kumar et al[26,35] reported 21 eyes (35%) that showed an average IOL tilting of 3.2 ± 2.7° on the horizontal axis and 2.9 ± 2.6° on the vertical axis as measured by anterior segment optical coherence tomography. No association was found between the postoperative BCVA and the degree of IOL tilting in these studies.

A Modified No-Assistant Glued SFIOL Technique

Narang et al[12] reported a no-assistant GSFIOL technique and compared it to a previously reported technique. After the leading haptic was externalized, the haptic was retrieved by the surgeon rather than the assistant. With this modified no-assistant technique, intraoperative complications including haptic kink (4% versus 24%), haptic breakage (0% versus 12%), haptic slippage (0% versus 8%), and IOL drop (0% versus 4%) were all lower. Although no direct head-to-head comparative study was available, the modified technique was associated with less immediate postoperative inflammation and a better BCVA at 1-week follow-up.[12]

Sutureless, Glueless SFIOL

Recently, sutureless, glueless SFIOL has gained popularity in clinical practice.[33] This technique is quicker to perform when compared to SSFIOL and the need of fibrin glue is obviated. It also retains the advantages of SFIOL over anterior chamber IOL.[62] In this systematic review, 12 studies were on sutureless, glueless SFIOL with a total of 463 eyes.[10,17,18,20,22,27,33,39,40,45,48,52]

Outcomes and Complications of Sutureless, Glueless SFIOL

The mean age at operation of this group was 59.23 ± 19.80 years with a mean preoperative BCVA of 0.67 ± 0.78, which improved to 0.33 ± 0.42 postoperatively. There were 23 IOL-related complications (4.97%) that included 2 IOL decentrations (0.55%),[45] 2 IOL tilting (0.55%),[27] 12 IOL optic captures (2.59%),[20,27,52] 3 IOL subluxations/dislocations (0.83%),[10] and 4 IOL haptic exposures/erosions (1.10%).[17,20]

For IOL decentration and tilting, measurements were available from Shuaib et al[20] who used ultrasound biomicroscopy and Chantarasorn et al[39] who used the Pentacam HR® tomographer (Oculus GmBH, Germany). The mean decentration of IOL from the optic center was 0.30 ± 0.39 mm. In addition to the above 2 studies, Yamane et al[52] used swept-source anterior segment optical coherence tomography to measure the IOL tilting, the average degree of IOL tilting was 3.30 ± 2.31°. Three studies reported a mean endothelial cell loss of 11.41% at a mean follow-up of 11.67 ± 5.51 months.[20,22,52]

SFIOL in Patients with Marfan Syndrome

We specifically reviewed the outcome and complications of SFIOL in Marfan syndrome. Patients with Marfan syndrome are genetically predisposed to subluxation of the crystalline lens due to zonular weakness. Patients may also present and require surgery at a younger age. Long-term stability and safety are of paramount importance in this group of patients. In this systematic review, there were 3 studies that included patients with Marfan syndrome with a total of 45 eyes.[7,9,43] The IOL fixation technique in all 3 studies were SSFIOL. In the study conducted by Lam et al,[43] the preoperative and postoperative characteristics of 4 eyes of patients with Marfan syndrome were analyzed. However, out of the 24 eyes in the study of Han et al,[9] only 2 eyes were from Marfan patients and the characteristics of these 2 eyes were not further specified, and thus were excluded from the analysis.

In the 43 included eyes of patients with Marfan syndrome, the mean age at the time of operation was 17.47 ± 9.21 years. In these 2 studies, both reported significant improvements in the BCVA after the operation. Lam et al[43] reported a change of LogMAR BCVA from 0.64 ± 0.23 preoperatively to 0.27 ± 0.16 postoperatively, whereas Zheng et al[7] reported a postoperative LogMAR BCVA of 0.22 ± 0.20 in their results. Only 1 study reported a postoperative endothelial cell loss of 19.50% at 1-year follow-up. In the same study, IOL decentration was reported in 19 eyes (44.19%) at 1 year as measured by anterior segment optical coherence tomography and ultrasound biomicroscopy. However, the study did not specify further details nor provided the amount of decentration. IOL optic capture was reported in 2 eyes (4.65%), making up a total of 21 IOL-related complications (48.84%).

SFIOL in Pediatric and Young Adult Patients

There were 9 studies that specified the use of SFIOL in pediatric and young adult populations (age < 30 years), including a total of 421 eyes with a mean age of 9.90 ± 4.86 years.[13,19,20,40–44,49] Among them, the surgical approach was SSFIOL in 7 studies,[13,19,41–44,49] and sutureless, glueless SFIOL approach in 2 studies.[20,40] The mean preoperative BCVA was 1.16 ± 0.89, which improved to 0.49 ± 0.60 postoperatively.

The indication for SFIOL in pediatric and young adult population was specified in 406 of 421 eyes.[13,19,20,41–44,49] In these 406 eyes, lens subluxation/dislocation contributed to 257 eyes of all cases (63.33%), including 134 eyes induced by trauma (33.00%),[42,44] congenital subluxation in 110 eyes (27.09%),[43,44] and 9 eyes secondary to Marfan Syndrome (2.22%).[42,43] Four eyes (0.99%) [20] did not specify the cause of lens subluxation. Cataract was the second most common indication in 87 eyes (21.43%). Among them, 52 were congenital cataracts (12.81%),[13,19,41,42,49] 31 were traumatic cataracts (7.64%),[13,19,41,49] and 4 were developmental cataracts (0.99%).[41] Other indications included 34 eyes with postoperative aphakia (8.37%),[20,42–44] 22 cases of IOL dislocation (5.42%),[42,44] 3 cases of traumatic perforation (0.74%),[42] and 3 cases of microspherophakia (0.74%).[20]

There were a total of 34 IOL-related complications (8.08%), 13 were subluxations/dislocations (3.09%),[44] 9 were optic captures (2.14%),[20,42,43,49] 3 were haptic exposures/erosions (0.71%),[40] and 8 were decentrations (1.90%).[13,41,49] Three suture-related complications were noted in the SSFIOL group (0.71%), all of which were suture erosions.[41,49] Shuaib et al reported 0.48 ± 0.57 mm of IOL decentration and $3.36 \pm 2.55^\circ$ of IOL tilting on ultrasound biomicroscopy and this study also reported a mean endothelial cell loss of 14.60% at a mean follow-up period of 6 months.

Elevated intraocular pressure and postoperative glaucoma were reported in 45 (6.31%) and 2 (4.00%) out of 396 and 50 eyes in 6 and 2 studies respectively.[13,20,41,42,44,49] Five of these studies used SSFIOL, whereas Shuaib et al[20] used sutureless, glueless approach.

There were 40 incidences of reoperation (9.50%) at a mean follow-up period of 21.58 ± 9.81 months. Sixteen were repaired for retinal detachment (3.80%),[44] 14 were refixation after IOL dislocation/decentration (3.33%),[41,44] 7 diode cyclophotocoagulation (1.66%),[44] 1 pupilloplasty was performed for an eccentric pupil (0.23%),[41] and 1 anterior membranectomy was performed for a persistent inflammatory fibrinous membrane across the anterior surface of the IOL (0.23%).[41] One patient had an exposed suture that eroded through the conjunctiva and required trimming postoperatively (0.23%).[49]

DISCUSSION

We have conducted a systematic review on the outcome and safety of 3 major types of SFIOL that included 2624 eyes, and summarized their complication profiles, impact on the corneal endothelium, and the position of IOL after implantation. Our review also included 421 eyes within the pediatric and young adult population, and 43 eyes with Marfan syndrome. Our results demonstrated that SSFIOL remained the most studied surgical option, especially in the unique patient populations mentioned above. Although other forms of SFIOL such as GSFIOL could achieve similar results in terms of IOL-related complications, endothelial cell loss, and IOL stability, one would have to bear in mind that there were far fewer studies and patient numbers reported for these techniques.

In terms of perioperative complications, all 3 types of SFIOL were similar and the risks of major postoperative complications such as retinal detachment, choroidal detachment, and infective endophthalmitis were all rare. SSFIOL was exclusively associated with suture-related complications that were not present in the other 2 types of SFIOL. Our systematic review could not demonstrate the effect of suture size and its association with the occurrence of suture-related complications.

In our review, we summarized the changes in corneal endothelial cell densities among the 3 techniques. The mean endothelial cell loss was comparable to the reported 7%–9% at 1 year from studies on routine phacoemulsification.[63–65] The confounding variables for endothelial cell analysis were often neither reported nor adjusted. Important factors such as anterior chamber depth, variation in phacoemulsification machine, ophthalmic viscoelastic device and infusion type, operative time, complexity of the case, experience of the surgeon, and whether combined procedures such as pars plana vitrectomy or lens removal was performed in the same session may contribute to the variability in endothelial cell count. We reviewed the operative times reported in the studies and found that the mean operative time was the shortest for GSFIOL in comparison to SSFIOL and sutureless, glueless SFIOL at 35.4 ± 4.03 min versus 45.7 ± 12.9 min versus 57.8 ± 10.7 min, respectively. This may explain the lowest endothelial cell loss reported in the GSFIOL group.

In terms of the IOL stability, decentration or tilting was present in approximately 10% of the eyes after implantation, with a mean of about 0.49 ± 0.40 mm decentration and $4.11 \pm 3.03^\circ$ of tilting. Holladay et al[66] reported a decentration of >1.00 mm could result in radial astigmatism and a tilting $>15^\circ$ could lead to coma aberration not correctable by spectacles alone. Although these outcomes were clinically relevant, the methods of measurement were highly variable and the gold standard is yet to be determined. Clinical examination remained the most commonly employed method to detect IOL tilting, but it was subjective and prone to observation bias. Anterior segment imaging may provide an objective and quantifiable result, but intermachine and interobserver variability remain. There was also no study on any association between minor decentration distance/degree of tilting and the final visual outcome.

Due to advancements in phacoemulsification machines, surgical microscopes, and the introduction of a continuous curvilinear capsulorhexis, the majority of cataract operations are uneventful and followed by an endocapsular implantation of an IOL. Furthermore, for subgroups such as children/young adults or Marfan syndrome, even fewer number of eyes would have undergone such operations. As a result, randomized controlled trials to directly compare various techniques of SFIOL from single centers would be difficult to conduct. Nonetheless, as the average life expectancy increases and patients receive cataract extraction earlier in life as compared to decades ago, ophthalmologists are now faced with an increased prevalence of IOL subluxation and/or dislocation that requires refixation of the malpositioned IOL or IOL exchange with various fixation techniques.

At the same time, SFIOL was frequently combined with other procedures such as concomitant vitreoretinal surgery or corneal transplantations, these procedures were often prolonged compared to IOL implantation alone. They would carry additional intraoperative risks and complications, and the visual prognoses of these eyes were different from those with cataracts or aphakia alone. In our systematic review, these studies were deliberately excluded to reduce their confounding effects to the pooled estimates of complication rates, visual outcomes, and endothelial cell changes.

By pooling and summarizing the existing data from multiple studies and surgeons performing a more homogenous surgical operation, our systematic review achieves a greater statistical power with larger sample size, and at the same time, the inclusion of multiple studies would closely reflect the “real-world” data in terms of outcomes after SFIOL.

SSFIOL was the technique with the longest history with roughly a 4-fold number of studies and an 8-fold number of eyes in comparison to the other 2 types of SFIOL. The imbalance in the size of the groups would impact the precision of the estimates in a systematic review, and it is possible that the results could favor the groups with smaller sample sizes. Furthermore, due to publication bias, adverse outcomes were not uniformly reported across all the studies and hence the safety profile of any type of SFIOL may be overestimated in a nondifferential manner. Meanwhile, none of the included studies reported any postoperative breakage of sutures. This is an important concern in SSFIOL as clinicians have been exploring alternative methods of scleral fixation, or using thicker or stronger suture instead of the conventional 10–0 propylene suture. In clinical practice, dislocation or subluxation of SFIOL as a result of suture breakage was occasionally encountered as a late complication that occurs approximately 10 years after surgery as the process of suture degradation is slow. The relatively short follow up period of 21.47 ± 16.41 months in the SSFIOL group may underestimate the suture breakage rate in real life. The same is applied to other long-term complications such as glaucoma and corneal decompensation that might have been underestimated in this systematic review.

Moreover, our review is further limited by the fact that we are comparing the results of different centers published across a span of 27 years, and these studies utilized different IOLs and instruments. The complexity of comparing eyes with multiple ocular comorbidities and different risk factors also pose challenges to the interpretation of this review. Furthermore, unfortunately, our review was not able to summarize the refractive outcome as individual data were not always available either in preoperative or postoperative period. The lack of information would limit the comparison of refractive predictability among the 3 types of SFIOL. Lastly, variations in the measurement devices, such as specular microscopy and the method of cell counting, and anterior segment imaging modality in determining the decentration and tilting of IOL, are additional limitations of this review. Nevertheless, to the best of our knowledge, the current review should have included the largest accumulative number of eyes with implanted SFIOL thus far.

In conclusion, all 3 types of SFIOL seemed to be safe in the majority of aphakic patients without sufficient capsular support. SSFIOL remained the most studied technique and the most popular option in unique patient populations such as young patients or Marfan syndrome. Future studies comparing glued and sutureless, glueless approaches in these unique populations may provide further insights as to the optimum method. Glued and sutureless, glueless SFIOL obviated the need for suture, with the potential for a shorter operation, good IOL stability, and no apparent additional harm to the corneal endothelium.

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