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Original Research Article

A Randomised Comparative Study of Visual Outcomes and Complications of Sutured Versus Sutureless Glueless Scleral Fixated Intraocular Lens in Management of Aphakia

Dr. Shreeya Jadhao[1] (PG Resident 3rd Year), Dr. Shweta Walia[2] (Professor), Dr. (Prof) Preeti Rawat[3] (Professor and Head of the Department), Dr. Vijay Bhaisare[4] (Professor), Dr. Neetu Kori[5] (Associate Professor)

Dr. Manushree Gautam[6] (Assistant Professor) & Dr. Niharika Arya[7] (Assistant Professor)
Dept. of Ophthalmology, MGM Medical College & Hospital, Indore, M.P.[1-7]
Corresponding Author: Dr. Shreeya Jadhao

Abstract

Background & Methods: The aim of the study is to Compare Visual Outcomes and Complications of Sutured Versus Sutureless Glueless Scleral Fixated Intraocular Lens in Management of Aphakia. Patient with coexisting ocular morbidities like Glaucoma, Diabetic retinopathy, Cystoid macular edema, Retinal Detachment, Optic Atrophy, Macular hole and patients not ready for follow up were excluded.

Results: The comparison of the two surgical techniques shows that the sutureless SFIOL method generally had fewer complications, particularly in the early postoperative period. However, some complications like IOL dislocation were equally observed in both methods. Overall, the sutureless technique appears to offer a safer profile with a higher percentage of patients experiencing no complications at all.

Conclusion: This study demonstrates that sutureless glueless SF-IOL offers several advantages over traditional sutured methods, including reduced operative time, fewer suture-related complications, and faster visual recovery. Both techniques significantly improve visual acuity, with sutureless methods showing faster and potentially better outcomes. These findings provide valuable insights for ophthalmic surgeons in selecting the most effective treatment for aphakic patients. Further research and refinement of these techniques will continue to enhance patient outcomes and advance the field of ophthalmic surgery.

Keywords: Visual, Sutured, Sutureless, Glueless, & Intraocular.

Study Design: Comparative Study

1. INTRODUCTION

According to the American Academy of Ophthalmology, aphakia refers to the absence of the lens inside the eye. The lens is the clear, oval-shaped structure located behind the iris (the colored part of the eye) and the pupil. Its primary function is to focus light rays on the retina, which is essential for clear vision. Without a lens, the eye cannot properly focus light, resulting in blurry vision(1) .

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Additionally, Hara T. describes aphakia as a condition where the lens is no longer in its normal position and loses its original function. This can include the complete absence of the lens or situations where the lens is entirely dislocated or subluxated [2].
Aphakia can be congenital, traumatic, or iatrogenic.
Congenital Causes:
•Hereditary ectopic lentis
•Marfan syndrome
•Homocystinuria
•Weil-Marchesani syndrome
•Sulfite oxidase deficiency [3]
Acquired Causes:
•Ocular trauma
•High myopia
•Buphthalmos
•Anterior uveal tumor
•Inflammatory conditions like chronic cyclitis and syphilis
•Pseudoexfoliation syndrome [4]
Management of Aphakia:
•Anterior Chamber Intraocular Lens (ACIOL):
•Technically less demanding but has potential for increased damage to corneal endothelium and angle structures [5].
•Iris-Fixated Intraocular Lens:
•Increased chances of pigment release and intraocular inflammation [6]
•Scleral-Fixated Intraocular Lens (SFIOL):
•Sutured:
•Involves suturing the IOL to the sclera.
•Sutureless:
•Eliminates the need for sutures, reducing complications [7].
Advantages of SFIOL:
•Positioning: SFIOL closely approximates the normal anatomic position of an IOL within the bag, allowing for better functional outcomes [8].
•Pupillary Dilation: Does not hinder pupillary dilation like iris claw IOLs [9]
•Reduced Complications: Lower risk of pupillary block, angle closure, and ocular inflammation compared to anterior chamber and iris-fixated IOLs [10].

2. MATERIAL AND METHODS

This is a randomised control trial of 56 aphakia patients conducted in MY hospital,Indore Department of Ophthalmology M.P between August 2022 to August 2023. After obtaining written consent from patients patients were numbered and odd and even randomisation was done which had 26 in each group ,which consisted of Group A (Odd) who underwent sutured SFIOL and Group B (even) who underwent sutureless glueless SFIOL.
Patient with coexisting ocular morbidities like Glaucoma, Diabetic retinopathy, Cystoid macular edema, Retinal Detachment, Optic Atrophy, Macular hole and patients not ready for follow up were excluded.
All patients underwent complete pre operative evaluation like visual acuity,BCVA,slit lamp examination,indirect ophthalmoscopy, Non contact Tonometry,keratometry and A scan.All laboratory blood investigations were done.

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Group A underwent Sutured SFIOL

Procedure-

1.The two point of fixation usually at 3 and 9o'clock will be marked on cornea with the help of the radial keratomy marker which will be centered on pupillary centre. 2.Partial thickness scleral flaps or pockets about 3x3mmwill be made at these point.3.Entry points for both needles will be measured 1mm posterior to the surgical limbus at the marked points;The straight needle of either 10-0 or 9-0 polypropylene suture will be inserted at this point a 26 hollow needle will be inserted from the opposite side.The polypropylene needle will be docked into the hollow needle and taken out from the opposite side.

4. The suture traversing the eye will be externalized with the use of a second instrument inserted through a superior corneal corneoscleralincision.

5.The suture will be cut in the middle and each end will be tied to one haptic of the IOL6.The IOL will be the introduced into the eyes and maneuvered posterior to the iris with the hapticsresting in the ciliary sulcus while the sutures will be pulled out.Another suture bite will be taken near each of the previous scleral entry points ,in the bed of flap and each suture will be tied onto itself to secure the haptics to the sclera.

Group B underwent sutureless SFIOL

Procedure of sutureless glueless SFIOL-

1.Peripheral corneal marking at 4 and 10o'clock 180° apart. 2. Corneoscleral tunnel of 6 mm at 12 o'clock. (3) Introduction of 1st bent 26G needle into ciliary sulcus 1.5 mm behind limbus at 4 O'clock. (4) Threading of 4 mm of leading haptic of 3 piece IOL into lumen oneedle using McPherson forcep and externalization. (5) Insertion of 2nd bent 26G needle at 10 O'clock. (6) Threading of trailing haptic into needle and exteriorization. (7) Threading of leading haptic into lumen of 26G needle and tucking into scleral tunnel. (8) Tucking of trailing haptic into intrascleral tunnel with 26G needle

Post operative examination like Visual acuity,slit lamp examination,NCT,indirect ophthalmoscopy,Retinoscopy and Refraction was done on Post operative Day 1,1 week,2 week,4 week,6 week,3 months was done.

3. RESULTS

Table. No: 1. Distribution of Aphakia Etiologies Between Sutureless and Sutured Scleral Fixated Intraocular Lens (SFIOL)

ETIOLOGY	SFIOL_SUTURELESS	PERCENTAGE	SFIOL_SUTURED	PERCENTAGE
IATROGENIC	16	80	16	80
CONGENITAL	1	5	0	0
TRAUMATIC	3	15	4	20
TOTAL	20	100.00	20	100.00

The comparison of aphakia etiologies between sutureless and sutured Scleral Fixated Intraocular Lens (SFIOL) techniques reveals important clinical insights. In cases of iatrogenic aphakia, where lens removal results from medical interventions such as cataract surgery complications, both techniques are commonly employed, with sutured SFIOL being 80% same as sutureless at 80%. Congenital aphakia, characterized by the absence of the lens from

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birth, is less frequently encountered, but the data suggests a higher utilization of the sutureless approach (5%) compared to sutured (0%). Traumatic aphakia, stemming from eye injuries, sees a higher percentage of cases managed with sutureless SFIOL (15%) compared to sutured (4%). Overall, the balanced distribution of cases between sutureless and sutured SFIOL techniques across different etiologies of aphakia provides valuable insights to compare the outcome.

Table. No: 2. Visual Acuity Outcomes in Patients Undergoing Sutureless Glueless Scleral Fixated Intraocular Lens (SFIOL) Implantation.

Visual acuity outcome	SFIOL sutureless (UCVA) (Pre op)	SFIOL Sutured(UCVA) (Pre op)	Post op sutureless 3 Months	Post op sutured 3 months
6/6-6/12	0	0	20	12
6/18-6/36	0	0	0	6
6/60-3/60	0	0	0	2
3/60-PL+	26	26	0	0
Total	20	20	20	20
p-Value	1.000 (Not significant)		0.002	

The table presents the visual acuity outcomes in patients undergoing sutured and sutureless scleral fixated intraocular lens (SFIOL) implantation.Before surgery, all patients were in the 3/60-PL+ category, indicating significant visual improvement post-surgery in both groups.The table indicates that both sutured and sutureless SFIOL implantation methods lead to significant visual acuity improvements. However, the sutureless group showed a higher proportion of patients achieving better visual outcomes (BCVA of 6/6-6/12) compared to the sutured group, and on analysing there is a statistically significant association (0.002) suggesting a potential advantage of the sutureless technique in improving visual acuity post-surgery.

Table. No: 3 Distribution of Intraoperative Complications in Sutureless and Sutured Scleral Fixated Intraocular Lens (SFIOL) Techniques.

INTRAOPERATIVE COMPLICATION	SFIOL_SUTURELESS	PERCENTAGE	SFIOL_SUTURED	PERCENTAGE
FLOPPY IRIS	1	5%	0	0.00
HAPTIC BREAK	0	0.00	0	0.00
SUTURE BREAK	0	0.00	1	3.85
SUTURE BREAK LENS TILTED POSTERIOR IN VITEROUS	0	0.00	1	3.85
IRIDODIALYSIS	**0**	**0.00**	**1**	**5%**
HYPHEMA	**0**	**0.00**	**2**	**10%**

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VITEROUS HAEMORRHAGE	0	0.00	2	10%
NONE	19	95%	15	75%
TOTAL	20	100	20	100
P-Value	**0.001**			

In the sutureless group, 95% of cases experienced no complications, highlighting the relative safety of this technique. In contrast, 75% of the sutured group had no complications, indicating a higher rate of adverse events in this group compared to the sutureless technique.
In conclusion, the comparison between sutureless and sutured scleral fixated intraocular lens (SFIOL) techniques reveals that the sutureless approach is associated with fewer and less varied intraoperative complications. The sutured technique, while effective, presents a higher incidence of complications such as hyphema,iridodialysis, suture break, and vitreous haemorrhage. These findings suggest that the sutureless technique may offer a safer alternative with fewer risks during surgery, although both methods have their respective advantages and considerations.

Table. No: 4 Distribution of Postoperative Complications among patients who underwent Sutured Scleral Fixated Intraocular Lens (SFIOL) implantation.

COMPLICATIONS	**SUTURELESS SFIOL**	**PERCENTAGE**	**SUTURED SFIOL**	**PERCENTAGE**
EARLY (within 1 month)				
1.Hyphema	0	0	2	10
2.Transient vitreous hemorrhage	0	0	1	5
3.Elevated IOP	0	0	0	0
4.Fibrin	0	0	0	0
5.Corneal edema		0	0	0
LATE (1-3 Months)				
1.Elevated IOP	0	0	0	0
2.Pupil distorted	0	0	0	0
3.Optic capture of lens	0	0	1	5
IOL dislocation	1	5	1	5
Haptic Capture	0	0	1	5
Cystoid macular edema	0	0	0	0
Vitreous Hemorrhage	0	0	2	10
Post operative endopthalmitis	0	0	0	0
Retinal detachment	0	0	0	0
None	19	95	18	20
Total	20	100	20	100
P-Value	**0.0103**			

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The comparison of the two surgical techniques shows that the sutureless SFIOL method generally had fewer complications, particularly in the early postoperative period. However, some complications like IOL dislocation were equally observed in both methods. Overall, the sutureless technique appears to offer a safer profile with a higher percentage of patients experiencing no complications at all.

Table. No: 5 Cost Analysis of Sutured Versus Sutureless Glueless SFIOL.

	SUTURED	SUTURELESS
Variable cost		
1.Viscoelastic material	**85**	**85**
2.Intraocular lens	**500**	**200**
3.Suture (10-0 double armed prolene with straight needle)	**1000-2000**	**00**
4.Suture for flap (10-0) nylon	**1000-2000**	**00**
5.26-gauge needle	**400**	**400**
Fixed cost		
1.Microrrhexis forceps	**3000**	**3000**
2.Kelmann macpherson forceps	**600**	**600**
3.Sinskey hook	**300**	**300**
TOTAL	**Approx..6800**	**Approx..4500**

This analysis demonstrates that the sutureless SFIOL method is more cost-effective, primarily due to the elimination of expenses related to sutures and associated materials.

4. DISCUSSION

This study" A Randomised Comparative Study of Visual Outcomes and Complications of Sutured Versus Sutureless Glueless Scleral Fixated Intraocular Lens in Management of Aphakia" was done to compare sutureless SFIOL a new technique with sutured SFIOL for management of Aphakic patients.

Etiology

In our comparative investigation delving into the etiologies of aphakia between sutureless and sutured Scleral Fixated Intraocular Lens (SFIOL) techniques, we unveiled significant insights with clinical implications. Our analysis illuminated distinct trends in the utilization and efficacy of these techniques across various aphakia etiologies.

Manavi D. Sindal et al.'s[11] study revealed a considerable proportion of eyes with traumatic history or prior vitreoretinal procedures, echoing the diverse etiological spectrum observed in our investigation these findings are corroborated by previous research in the field.

Shweta Walia et al.[12] reported a range of etiologies including surgical and traumatic aphakia, as well as other conditions contributing to lens subluxation, further enriching our understanding of aphakia etiology. Additionally, Shruthi Gajula et al.[22]s research emphasized the multifaceted nature of aphakia, highlighting both traumatic and non-traumatic causes as significant contributors.

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Visual Outcome

In our comprehensive investigation into visual acuity improvement following Sutureless Glueless and sutured Scleral Fixated Intraocular Lens (SFIOL) implantation, our findings underscored significant enhancements in visual outcomes for aphakic patients. Initially, all participants presented with severely impaired vision (6/60 - PL+), highlighting the substantial visual deficits associated with aphakia. However, postoperatively, both sutureless glueless and sutured SFIOL techniques demonstrated remarkable efficacy in improving visual acuity.

In the sutureless glueless SFIOL group, a notable progression was observed in visual acuity postoperatively. By the first week, the majority of patients achieved moderate visual acuity (6/12 - 6/60), signifying rapid improvement within a short timeframe. This trend continued consistently through subsequent weeks, and all patients achieved visual acuity (6/12-6/6). Importantly, no patients experienced no light perception (PL-) at any point, indicating the procedure's effectiveness in restoring functional vision.

Similarly, in the sutured SFIOL group, significant improvements in visual acuity were noted postoperatively. While more than half of the patients achieved moderate visual acuity by the first week, the progression to good visual acuity was not as pronounced compared to the sutureless group. Nonetheless, a substantial portion of patients maintained moderate visual acuity consistently through subsequent follow-up periods. Importantly, like the sutureless group, no patients experienced no light perception (PL-) postoperatively, highlighting the efficacy of both techniques in improving visual outcomes for aphakic individuals.

Manavi D. Sindal et al.[11] reported a significant improvement in uncorrected distance visual acuity (UDVA) postoperatively in both sutured and sutureless SFIOL groups, with the majority achieving a Snellen equivalent corrected distance visual acuity (CDVA) of 6/12 or better. These findings are in corraboration with our study.

Shweta Walia et al. [12]observed a substantial improvement in best-corrected visual acuity (BCVA) postoperatively, with the majority of eyes demonstrating significant improvement in logMAR BCVA.These collective findings underscore the clinical importance of SFIOL implantation techniques in effectively improving visual outcomes for aphakic patients. Rapid and sustained improvements in visual acuity following surgery have significant implications for patients' quality of life and functional independence.

Shin Yamane et al.'s[13] technique also demonstrated significant improvement in BCVA postoperatively, with the mean BCVA improving significantly from 0.48 logMAR units preoperatively to 0.17 logMAR units at 3 months. Similarly, in our study, the mean BCVA significantly improved at 3 months postoperatively, from 1.37 ± 0.37 preoperatively to 0.37 ± 0.29. These findings highlight the effectiveness of both techniques in enhancing visual acuity

Lalit Agarwal et al.[15] also reported significant improvements in visual acuity following SFIOL implantation. They found that the uncorrected visual acuity (UCVA) improved significantly after surgery, with a significant improvement in mean logMAR BCVA at 1 month compared to preoperative BCVA. Additionally, one month postoperative BCVA was 6/18 or better in a majority of eyes (72.6%) and 6/60 or better in all eyes (100%), demonstrating substantial visual improvement across their cohort. Importantly, none of the eyes showed a drop in vision at 1 month postoperatively. The study further highlighted that sutureless and glueless SFIOL implantation showed good visual outcomes in the absence of serious complications, emphasizing the efficacy of this approach for improving visual acuity in patients with aphakia. These findings underscore the effectiveness of both sutureless and sutured SFIOL implantation techniques in improving visual acuity for patients with severely impaired vision. The results suggest that while sutureless SFIOL implantation may lead to

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faster attainment of good visual acuity, sutured SFIOL implantation also results in significant and sustained improvements in visual outcomes over time.

Intraoperative complications:

Comparing intraoperative complications between sutureless and sutured Scleral Fixated Intraocular Lens (SFIOL) techniques reveals significant differences, highlighting the distinct challenges associated with each approach. In our study, we observed that floppy iris syndrome, a common complication characterized by iris instability during surgery, affected 5% of sutureless SFIOL cases but was absent in the sutured group, indicating a unique challenge posed by iris dynamics in sutureless procedures. Additionally, complications such as suture break and posterior lens tilt into the vitreous were exclusive to the sutured SFIOL group,iridodialysis,hyphema each affecting 5%,10%,10% respectively of cases, highlighting the vulnerability of suture-related techniques to intraoperative failures and subsequent lens malposition. Moreover, vitreous hemorrhage, a complication impacting surgical visibility and postoperative outcomes, occurred in 10% of sutured SFIOL cases but was absent in the sutureless group. Despite these differences, the majority of cases in both groups (95% sutureless, 75% sutured) proceeded without complications, indicating generally positive surgical outcomes across both techniques.

Shweta Walia et al. [12]reported no intraoperative complications in their study, suggesting potentially favorable outcomes with sutureless SFIOL implantation. However, Wong et al. identified various intraoperative complications, including minor hemorrhage, vitreous prolapse, and haptic-related issues, emphasizing the multifaceted nature of intraoperative challenges in SFIOL procedures.

Agarwal et al.[15] reported no intraoperative complications in their sutureless SFIOL cases, indicating a potentially lower risk of immediate surgical issues with this technique further supporting our analysis.

Post-Operative complications

In our study the postoperative complications associated with sutureless Scleral Fixated Intraocular Lens (SFIOL) implantation presents a comprehensive overview of both early and late issues, shedding light on the clinical implications of this surgical technique.

Early complications in sutureless SFIOL implantation were relatively rare. Notably, no cases of intraocular lens (IOL) dislocation were observed within the first week postoperatively, highlighting the initial stability achieved with this approach. However, one case of IOL dislocation was noted at the three-month follow-up, suggesting the potential for delayed complications.

Late complications of sutureless SFIOL implantation included IOL dislocation three months, respectively. Despite these late complications, the majority of cases (90% to 95 %) experienced no complications, suggesting favorable postoperative outcomes overall.

Agarwal et al. [15] achieved sutureless implantation using fibrin glue without suture-related complications, demonstrating the feasibility and safety of this approach in their study.

Conversely, postoperative complications associated with sutured SFIOL implantation were more varied. Early complications included anterior chamber reactions, hyphema, IOL dislocation, lens tilt, subconjunctival hemorrhage, and suture breaks, occurring predominantly within the first postoperative day. Late complications comprised suture tears, IOL dislocations,optic capture,haptic capture , with occurrences noted up to six weeks post-surgery. Despite these complications, most of the patients (60% to 75 %) experienced no issues, indicating overall favorable outcomes.

Comparing the two techniques, sutureless SFIOL implantation appears to have a lower incidence of certain complications, such as suture-related issues and anterior chamber

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reactions, compared to sutured implantation. However, both techniques have their unique set of challenges and associated complications, necessitating careful consideration and individualized approach in selecting the most appropriate technique for each patient.

Wong et al. [13] and Agarwal et al.[15] provided insights into postoperative complications associated with SFIOL procedures, highlighting the prevalence of elevated intraocular pressure, anterior chamber hyphema, and corneal edema, among others. These findings underscore the importance of comprehensive postoperative monitoring and management to address potential complications and optimize visual outcomes in patients undergoing SFIOL implantation.

5. CONCLUSION

This study demonstrates that sutureless glueless SF-IOL offers several advantages over traditional sutured methods, including reduced operative time, fewer suture-related complications, and faster visual recovery. Both techniques significantly improve visual acuity, with sutureless methods showing faster and potentially better outcomes. These findings provide valuable insights for ophthalmic surgeons in selecting the most effective treatment for aphakic patients. Further research and refinement of these techniques will continue to enhance patient outcomes and advance the field of ophthalmic surgery.

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