ARTIKEL PENELITIAN

EFFICACY AND SAFETY ANALYSIS OF SCLERAL FIXATION INTRAOCULAR LENS IMPLANTATION USING THE YAMANE TECHNIQUE

ANALISIS EFIKASI DAN KEAMANAN DARI IMPLANTASI LENSA INTRAOKULAR FIKSASI SKLERAL DENGAN MENGGUNAKAN TEKNIK YAMANE

Stephanus Anggara^{1,2,*}, Siska², I Wayan Jayanegara², Putu Dian Megasafitri², Ni Made Kartika Rahayu³

- ¹ Ophthalmology Resident, Ophthalmology Program Study, Faculty of Medicine, Udayana University, Jl. P.B. Sudirman, Kampus Sudirman, Denpasar, Bali 80232
- ² Department of Ophthalmology, Prof. I.G.N.G. Ngoerah Hospital, Jl. Diponegoro, Denpasar, Bali 80113
- ³ Ramata Eye Hospital, JI. Gatot Subroto Barat No. 429, Denpasar, Bali 80117

* Correspondence: stephanus.anggara@gmail.com

ABSTRAK

Pendahuluan: Teknologi operasi katarak terus dikembangkan untuk mengatasi komplikasinya. Metode bedah terkini untuk lensa intra okuler (intra ocular lens/IOL) sekunder meliputi IOL Ruang Anterior, IOL Iris Claw, dan teknik IOL fiksasi skleral (scleral fixation intra ocular lens/SFIOL) yang dijahit dan tanpa jahitan. Teknik Yamane dari SFIOL adalah metode SFIOL tanpa jahitan yang baru, relatif aman dan mudah. Penelitian ini bertujuan untuk mendeskripsikan dan menganalisis hasil bedah dan komplikasi teknik implantasi IOL Yamane. **Metode:** Penelitian retrospektif pada 21 mata dari 21 pasien yang menjalani fiksasi IOL scleral dengan teknik Yamane diamati. Data demografi, indikasi utama pembedahan, koreksi ketajaman penglihatan terbaik (best corrected visual acuity, BCVA) dan tekanan intraokular (intraocular pressure/IOP) sebelum operasi dan pasca operasi selama masa tindak lanjut, dan komplikasi dianalisis.

Hasil: Dua puluh satu pasien diikutsertakan dalam penelitian ini dengan usia rata-rata 52,57±23,41 tahun. 11 mata dengan subluksasi lensa (52,4%), 9 mata dengan aphakia (42,9%), dan 1 mata dengan phacodonesis (4,8%) diindikasikan untuk teknik Yamane SFIOL dalam penelitian ini. Rata-rata BCVA sebelum operasi adalah 2,2±0,9 LogMAR sedangkan BCVA 1 bulan pascaoperasi adalah 1,1±0,9 LogMAR. Rerata IOP sebelum operasi adalah 15,81±6,7 mmHg dan IOP 1 bulan pascaoperasi adalah 16,00±7,7 mmHg. Penelitian ini mendapatkan peningkatan BCVA yang signifikan dengan p=0,00 (p<0,05), dan tidak terdapat lonjakan IOP paska operasi yang signifikan dengan p=0,88 (p<0,05). Komplikasi utama yang diamati dalam penelitian ini adalah edema kornea (23,8%), dan lonjakan IOP pascaoperasi (14,3%).

Simpulan: Teknik Yamane SFIOL adalah pendekatan yang relatif aman untuk manajemen bedah pasien yang memerlukan implantasi IOL sekunder dengan peningkatan fungsi penglihatan secara signifikan tanpa komplikasi yang signifikan.

Kata Kunci: katarak, IOL fiksasi skleral, teknik Yamane

ABSTRACT

Introduction: Cataract surgery technologies continue to manage complications. Current surgical methods for secondary Intra Ocular Lens (IOL) include Anterior Chamber IOL, Iris Claw IOL, and sutured and sutureless techniques of Scleral Fixation IOL (SFIOL). The Yamane technique of SFIOL is a novel, relatively safe, and easy method of sutureless SFIOL. This study aims to describe and analyze the surgical outcomes and complications of the Yamane IOL implantation technique.

Methods: A retrospective study of 21 eyes of 21 patients that underwent scleral fixation of IOL by the Yamane technique was observed. Demographic data, primary indications for surgery, best corrected visual acuity (BCVA), intraocular pressure (IOP) pre-operative and post-operative during follow-up, and complications were also analyzed.

Results: Twenty-one patients were included, with an average age of 52.57±23.41 years old. Eleven eyes with lens subluxation (52.4%), 9 eyes with aphakia (42.9%), and 1 eye with phacodonesis (4.8%) were indicated for the Yamane technique of SFIOL in this study. The preoperative mean BCVA was 2.2±0.9 LogMAR, while

the 1-month postoperative BCVA was $1.1\pm0.9 \text{ LogMAR}$. The mean preoperative IOP was $15.81\pm6.7 \text{ mmHg}$, and the 1-month postoperative IOP was $16.00\pm7.7 \text{ mmHg}$. This study found that there was a significant improvement in BCVA with p=0.00 (p<0.05), and there was no significant postoperative IOP spike with p=0.88 (p<0.05). The main complications observed in this study were corneal edema (23.8%) and postoperative IOP spike (14,3%).

Conclusion: The Yamane SFIOL technique is a relatively safe approach for the surgical management of patients who need secondary IOL implantation with significantly improved visual function without significant complications.

Key Words: cataract, scleral fixation IOL, Yamane technique

INTRODUCTION

Ideal IOL placement is in a capsular bag, which is only sometimes possible due to a lack of capsular support. Various conditions, such as trauma, previous eye surgery, genetic causes, such as Marfan syndrome or homocystinuria, pseudoexfoliation syndrome, and inflammation, can cause inadequate capsular support. The IOL can be placed in the sulcus if partial capsular support is available. If there is no capsular support, the IOL can be placed in the anterior chamber with fixation to the iris or sclera, either using or without sutures. Each method has advantages and disadvantages that must be considered.¹

Cataract complications are decreasing along with the sophistication of technology and surgical techniques. However, this does not rule out the possibility of complications occurring.² Complications that can arise intraoperatively but will resolve on their own include subconjunctival bleeding, chemosis, and corneal abrasion. Other intra-operative complications are thermal injury, detachment of Descemet's membrane, intra-operative floppy iris syndrome (IFIS), Femto-second Laser-Associated Miosis, Lens-iris diaphragm retropulsion syndrome (LIDRS), iridodialysis and iris trauma, cyclodialysis, shallowing of the anterior chamber, anterior capsule tear, posterior capsule rupture, and intraoperative bleeding.³ Complications after cataract surgery include corneal edema (0.03-5.18% of cases), retained lens fragments (0.45-1.70% of cases), IOL dislocation (0.19-1.10% cases), posterior capsule opacification, myopic shock, endophthalmitis (0.04-0.20% of cases), cystoid macular edema (1.2-3.5% of cases), and retinal detachment (0.7% of cases).⁴

Cataract surgery technology continues to be developed to prevent complications during and after cataract surgery. IOL fixation is one of the critical steps in cataract surgery. One of the IOL fixation techniques is fixing the haptic to the sclera, called the Yamane technique. Yamane technique is meant to externalize the three-piece IOL haptics with 30- or 27gauge needles through 180° apart transconjunctival sclerotomies and make a flange at the end of the haptics with low-temperature cautery to prevent the haptics from prolapsing back into the posterior chamber¹. Previous studies show that Yamane techniques have advantages over other techniques that can cause corneal endothelial cell loss, glaucoma, and peripheral anterior synechiae to fix the IOL efficiently in the posterior segment in the absence of capsular support.⁵ As such, the purpose of the current study was to analyze the outcomes and complications of Yamane techniques.

METHODS

This is an analytical study with a retrospective study approach. Data was collected by recording the characteristics of patients who had undergone scleral fixation intraocular lens implantation using the Yamane technique from January 2022 to June 2023. This research data includes gender, age, domicile, indications for implantation, surgical complications, visual acuity, and intraocular pressure compared before and 30 days after surgery. The research was conducted at the eye polyclinic of RSUP I.G.N.G. Prof. Ngoerah Denpasar and Ramata Eye Hospital, Denpasar, Bali.

All patients who underwent scleral fixation intraocular lens implantation using the Yamane technique during the study period were included. Patients with incomplete evaluation data, including preoperative condition, 30-day postoperative visual acuity data, intraocular pressure, and endothelial cell count, cases with vitreoretinal problems involving the macula, history of corneal rupture, or with traumatic optic neuropathy with low visual potential were excluded.

Analysis of outcomes was carried out using the paired T-test if the data was normally distributed and the Wilcoxon Signed Ranks Test if the data was not normally distributed.

RESULTS

Twenty-one eyes were included in this study. The demographic characteristics of research subjects can be seen in Table 1. Most patients were male, namely 15 patients (71.4%). The mean age of patients was 52.57 \pm 23.41 years. Most participants were in the 61–70-year age group with 5 patients (23.8%). Most patients live in Denpasar, namely 20 patients (95.2%). There was 1 patient came from outside Bali, namely from East Nusa Tenggara province (4.8%).

| Characteristics | n (%) |
|-----------------|---------------|
| Age(s) (year) | 52.57 ± 23.41 |
| Sex | |
| Male | 15 (71.4) |
| Female | 6 (28.6) |
| Domicile | |
| Bali | 20 (95.2) |
| Outside Bali | 1 (4.8) |

The most frequent indication for secondary IOL implantation surgery using the Yamane Technique was lens subluxation with a total of 11 patients (52.4%), followed by post-operative aphakia in 9 patients (42.9%) and post-traumatic phacodonesis in 1 patient (4.8%). The side of the eye operated on mainly was the left eye, 12 eyes (57.1%). All patients only underwent surgery on 1 eye (unilateral). The clinical characteristics of the research subjects can be seen in Table 2.

The differences in visual acuity before and after implantation of a scleral fixation intraocular lens using the Yamane technique are shown in Table 3. There was a significant increase in visual acuity from 2.24 \pm 0.91 logMAR before implantation to 1.19 \pm 0.92 logMAR at 30-day follow-up (p <0.00).

| Table 2. Clinical Characteristics of Research Subjects | | | |
|--|-----------|--|--|
| Characteristics of Research Subjects | n (%) | | |
| Operation indications | | | |
| Post operation aphakia | 9 (42.9) | | |
| Lens subluxation | 11 (52.4) | | |
| Post traumatic phacodonesis | 1 (4.8) | | |
| Operated eye | | | |
| Oculi Dextra (OD) | 9 (42.9) | | |
| Oculi Sinistra (OS) | 12 (57.1) | | |

 Table 3. Differences in Visual Acuity Before and After Scleral Fixation Intraocular Lens Implantation

 Using the Yamane Technique (logMAR)

| Mean of Visual Acuity (logMAR) ± SD | | p-Value |
|-------------------------------------|-------------|---------|
| Pre Operation | 2.24 ± 0.91 | -0.00* |
| Post Operation 30 Days | 1.19 ± 0.92 | <0.00* |

* p-value was calculated using the Wilcoxon Signed Ranks Test

Table 4. Differences in IOP Before and After Scleral Fixation Intraocular Lens Implantation

 Using the Yamane Technique

| Mean of Intraocular Pr | p-Value | |
|---|--------------|---------|
| Pre Operation | 13.83 ± 3.97 | <0.795* |
| Post Operation 30 Days | 14.28 ± 4.68 | <0.795 |
| * p-value was calculated using the Wilcoxon Signed Ranks Test | | |

Table 5. Complications of Scleral Fixation Intraocular Lens Implantation Using the Yamane Technique

| Complications | n (%) |
|----------------------|------------|
| Corneal edema | 5 (23.8) |
| IOP increment | 3 (14.3) |
| Without complication | 13 (61.9%) |

The difference in intraocular pressure (IOP) during scleral fixation intraocular lens implantation using the Yamane technique is shown in Table 4. Obtained IOP before implantation with a mean of 15.81 ± 6.7 mmHg and IOP after 30 days post implantation with a mean of 16.00 ± 7.7 mmHg. The two groups were then tested using the Wilcoxon Signed

Ranks Test and showed that there was no difference between IOP before and after 30 days after IOL implantation (p=0.795).

In this study, there were 8 patients who experienced complications 30 days after scleral fixation intraocular lens implantation using the Yamane technique. Five patients (23.8%) experienced complications of corneal edema, and 3 patients (14.3%) experienced complications of increased intraocular pressure. The remaining 13 patients (61.9%) had no complications related to scleral fixation intraocular lens implantation with the Yamane technique.

DISCUSSION

The technique of scleral fixation IOL implantation was first described more than 30 years ago. Since then, there has been an improvement in the safety profile of various IOL implantation techniques as more research has provided a better understanding of possible complications and strategies to reduce the incidence of complications. In general, IOL implantation with fixation to the sclera offers several anatomical advantages compared with IOL implantation in the anterior segment. Because IOL implantation with fixation to the sclera is located more posteriorly, there is a hypothetical higher probability of preserving the integrity of the anterior segment by minimizing damage to the corneal endothelium, disruption of the trabecular body, narrowing of the anterior chamber, or formation of peripheral anterior synechiae.6

This research was conducted by looking at the clinical picture and results of IOL implantation surgery with fixation to the sclera. The research sample in this study showed more men than women. This aligns with studies by Raina et al. and Rocke et al., which have a similar composition.^{2,3} The main indications for the IOL implantation procedure using the Yamane technique in this study include aphakia, followed by lens subluxation and then post-traumatic phacodonesis. This is in line with research by Sahin et al., namely in his research involving 30 research subjects, which showed that the main indication for IOL implantation with the intrascleral Yamane technique included aphakic conditions, with 24 research subjects, followed by 5 subjects with lens dislocation and 1 subject with IOL dislocation.⁷ Other research by Shelke et al. also showed that 17 subjects out of 46 total samples (36%) were patients with aphakia, followed by 9 patients with lens dislocation (19%) and 6 patients with IOL dislocation (13%).8 Aphakia conditions can occur due to complicated cataract surgery, such as after removal of a lens that has subluxated/dislocated or after explantation of an IOL that has shifted position. Visual rehabilitation in these cases mostly requires secondary IOL implantation, either as a procedure carried out simultaneously with the lens/IOL explantation procedure or as a secondary procedure carried out later in stages.8

This study shows that there is a significant difference in visual acuity between before and after surgery. Several previous studies also showed that visual acuity after IOL implantation with the intrascleral Yamane Technique resulted in significant visual acuity, which in research by Patel et al. showed that as many as 384 eyes (78.7) achieved desired refractive outcome within ±1.0 diopter from the target refraction result from the target refraction result.⁹ Another study also showed that subjects experienced an increase in visual acuity after surgery of Intrascleral IOL implantation.¹⁰⁻¹⁶

In general, this study shows that there is no statistically significant difference in intraocular pressure before and after surgical implantation. This is similar to the findings of several other studies, which show there is no adequate evidence that IOL implantation with the Yamane technique causes permanent changes in intraocular pressure or triggers the onset of glaucoma. Most studies show that there is an increase in eye pressure that can respond to topical antiglaucoma eye drops and that these changes are temporary.^{9,10}

Zhao et al. found that the most common complication after IOL implantation with the Yamane technique is corneal edema at 10.1%.¹⁰ Patel et al. found that the complications that occurred were cystoid macular edema as the most common complication in their study (7.6%) followed by corneal edema (7.1%) and increased intraocular pressure (5.3%). Various studies show that patients after secondary IOL implantation generally experience complications due to chronic inflammation, such as cystoid macular edema, pseudophakic bullous keratopathy, and uveitis-glaucoma-hyphema syndrome. However, most of these complications can be treated with conservative medical therapy.¹⁷⁻²⁰ This study also reported similar findings but found that the most common complication after IOL implantation with the Yamane Technique was corneal edema followed by an increase in intraocular pressure. In this study, there were no complications of cystoid macular edema. The complications in this study were only temporary and improved with the use of hyperosmolar eye drops.9

CONCLUSION

In this study, patients who underwent IOL implantation with fixation on the sclera were patients with the main indication of aphakia and followed by an indication of lens subluxation. The patient experienced improved visual acuity after 30 days of implantation. There were five patients complicated by corneal edema and 3 patients complicated by a temporary increase in intraocular pressure, but in general, there was no significant difference in intraocular pressure before and after implantation.

This study has some limitations, such as the retrospective nature of the current study and incomplete reporting of the variability of the indications and surgeon factors during surgery. A larger cohort would enable more conclusive findings about the problems and outcomes of the Yamane technique. In conclusion, there was a significant improvement in visual acuity before and after surgery. These results provide insight into the good visual results offered by this technique with adequate scleral haptic fixation without using adjuvants without significant complications in the postoperative course.

REFERENCES

- American Academy of Ophthalmology. AAO BCSC Section 11: Lens and Cataract. San Fransisco: American Academy of Ophthalmology; 2023.
- Raina UK, Kumar B, Bhattacharya S, Saini V, Gupta SK, Goyal J. A comparison of sutureless flanged fixation and 4-point gore-tex fixation for scleral-fixated intraocular lenses: A pilot study. Digit J Ophthalmol. 2022; 28(3):51-57.
- Rocke JR, McGuinness MB, Atkins WK, Fry L, Kane JX, Fabinyi DCA, et al. refractive outcomes

of the Yamane flanged intrascleral haptic fixation technique. Digit J Ophthalmol. 2020; 127(10):1429-1431

- Yamane S, Sato S, Maruyama-Inoue M, Kadonosono K. Flanged intrascleral intraocular lens fixation with double-needle technique. Ophthalmology. 2017; 124(8):1136–1142.
- Ifantides C, Naids SM, Muttuvelu DV, Mian SI, Christopher KL. A modified flanged intrascleral intraocular lens fixation technique using an externalized needle for haptic docking. Clin Ophthalmol. 2021; 15:2047-2050.
- Shahid SM, Flores-Sánchez BC, Chan EW. Scleral-fixated intraocular lens implants-evolution of surgical techniques and future developments. Eye (Lond). 2021; 35(11):2930-2961.
- Sahin Vural G, Guven YZ, Karahan E, Zengin MO. Long term outcomes of Yamane technique in various indications. Eur J Ophthalmol. 2023 Nov;33(6):2210-2216.
- Shelke K, Rishi E, Rishi P. Surgical outcomes and complications of sutureless needle-guided intrascleral intraocular lens fixation combined with vitrectomy. Indian J Ophthalmol. 2021; 69(9):2317-20.
- Patel V, Pakravan P, Lai J, Watane A, Mehra D, Eatz TA, et al. Intraocular lens exchange: Indications, comparative outcomes by technique, and complications. Clin Ophthalmol. 2023 Mar 23;17: 941-51.
- Zhao H, Wang W, Hu Z. Long-term outcome of scleral-fixated intraocular lens implantation without conjunctival peritomies and sclerotomy in ocular trauma patients. BMC Ophthalmol. 2019; 164.
- Bodin S, Bourdon H, Bennedjai A. Efficacy and safety of intraocular folding sutureless scleral fixating lens versus iris-claw intraocular lens implantation. J Fr Ophtalmol. 2022;45(4):392-397.
- Madhivanan N, Sengupta S, Sindal M, Nivean PD, Kumar MA, Ariga M. Comparative analysis of retropupillary iris claw versus scleral-fixated

intraocular lens in the management of post-cataract aphakia. Indian J Ophthalmol. 2019;67(1):59-63.

- Forlini M, Bedi R. Intraocular lens implantation in the absence of capsular support: scleral-fixated vs retropupillary iris-claw intraocular lenses. J Cataract Refract Surg. 2021;47(6):792-801.
- Kansal V, Onasanya O, Colleaux K, Rawlings N. Outcomes of using sutureless, scleral-fixated posterior chamber intraocular lenses. Semin Ophthalmol. 2019;34(7-8):488-496.
- Raimondi R, Sorrentino T, Kilian R. Trans-scleral plugs fixated FIL SSF IOL: A review of the literature and comparison with other secondary IOL implants. J Clin Med. 2023;12(5):1994.
- Armonaite L, Behndig A. Repositioning of in-thebag dislocated intraocular lenses: a randomized clinical trial comparing two surgical methods. Ophthalmic Res. 2023;66(1):590-598.
- 17. Czajka MP, Frajdenberg A, Stopa M, Pabin T, Johansson B, Jakobsson G. Sutureless intrascleral fixation using different three-piece posterior chamber intraocular lenses: A literature review of surgical techniques in cases of insufficient capsular support and a retrospective multicentre study. Acta Ophthalmol. 2020;98(3):224-236.
- Chang YM, Weng TH, Tai MC. A meta-analysis of sutureless scleral-fixated intraocular lens versus retropupillary iris claw intraocular lens for the management of aphakia. Sci Rep. 2024;14(1): 2044.
- Karadag R, Celik HU, Bayramlar H, Rapuano CJ. Sutureless intrascleral fixated intraocular lens implantation. J Refract Surg. 2016;32(9):586-597.
- Taskin I, Altinbay D, Ozdemir VN. A different surgical approach to cases with zonular weakness or dialysis: Sutureless transscleral fixated intraocular lens implantation and stabilization of lens capsule. Int Ophthalmol. 2020;40(9):2315-2323.