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Research Article

Stability and Effectiveness of Tecsoft™ Acrylic Hydrophilic Intraocular Lens with its Outcome in Nepalese Population: A 2-Year Review

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Abstract

Background: Advances in surgical procedures have allowed for minimally invasive cataract surgery procedures such as phacoemulsification with foldable intraocular lens implantation. However, the ideal foldable intraocular lens which is cheap, stable and effective has yet to be determined. This study attempts to assess the stability and effectiveness of Tecsoft Sterile Foldable acrylic Intraocular Lenses for primary visual correction following uncomplicated phacoemulsification surgery.

Materials and Methods: Retrospective analysis of case records of 174 eyes of 114 patients who had undergone phacoemulsification with insertion of Tecsoft Sterile Foldable Acrylic Intraocular lenses from September to November 2016 was done for 2 years after surgery. Demographic parameters of patients and stability and efficacy of lenses in providing good postoperative outcome was assessed in terms of visual acuity, rates of postoperative iritis, postoperative rise of intraocular pressure, corneal edema, IOL decentration, PCO formation and anterior capsule fibrosis.

Results: Excellent visual and refractive outcomes and stability were demonstrated. At postoperative visit 4 week 96.6% of subjects achieved a Snellen best-corrected distance visual acuity (BCVA) of 6/6 to 6/18 (Log MAR 0.0 - 0.5), and 98.3% of subjects achieved a BCVA of 6/18-6/60 (LogMAR 0.50 - 1.0) or better. At final visit in 2 years, after Neodymium:yttrium aluminum garnet (Nd:YAG) capsulotomy for Posterior Capsular Opacification (PCO) where necessary, 98.3% patients had a BCVA of 6/6-6/18 (0.0 - 0.5) and all patients had a BCVA of better than 6/60 (Log MAR 1.0). Adverse events were infrequent and were consistent with incidences generally reported with cataract surgery.

Conclusion: Tecsoft Sterile Foldable Acrylic Intraocular lens (Hydrophilic, Posterior Chamber) was found to be efficient both in terms of visual outcome and stability and results were comparable to other hydrophilic lenses.

Keywords: *Posterior Capsular Opacification (PCO); Tecsoft; Intraocular Lens*

Introduction

Cataract surgery is known to be the commonest and most rewarding ocular surgery performed worldwide. Approximately 12 to 15 million patients receive an IOL implantation each year [1]. Many companies have launched different materials and different designs of

IOLs in view of stability, biocompatibility and effectiveness of visual rehabilitation. Common materials include hydrophilic and hydrophobic acrylic IOLs such as Poly (2-hydroxyethyl methacrylate) material (also called Poly-HEMA), Poly methyl methacrylate (PMMA) and silicone. Common designs include rounded, open loop and closed loop and square edged haptic designs in foldable or rigid materials. Each material and design has its own array of advantages and disadvantages. This article attempts to assess the safety, biocompatibility and effectiveness of Tecsoft Sterile Foldable Acrylic Intraocular lens over a 2 year period. Launched in 2005 by The Fred Hollows Intraocular Lens Laboratory in Nepal, the Tecsoft Sterile Foldable Acrylic Intraocular lens is among the most economical means of primary visual rehabilitation after phacoemulsification surgery.

Subjects and Methods

Study design

Retrospective, observational case series was performed through electronic medical recording database at Tilganga Institute of Ophthalmology.

This study was performed by approval of the institutional review committee (IRC) of Tilganga Institute of Ophthalmology and adheres to the tenets of the Declaration of Helsinki.

The Tecsoft Sterile Foldable Acrylic Intraocular lenses manufactured by The Fred Hollows Intraocular lens Laboratory meet all the Regulatory Requirements of Optical property, Mechanical Property, Sterility, Ethylene oxide residue testing and biocompatibility as per the relevant ISO Standards.

Eligibility criteria

The inclusion criteria were all cases of uneventful cataract surgery of uncomplicated cataract in patients of 40 years of age or above. Patients with corneal opacity, glaucoma, ocular inflammations, amblyopia, traumatic cataract, diabetic retinopathy or any other retinal conditions with poor visual prognosis were excluded.

Study procedures

Retrospective review of charts of patients that had undergone uncomplicated cataract surgery between September 2016 to November 2016 was done. Information collected included demographic parameters like gender, age, ethnicity, literacy rate, and presence of systemic diseases such as hypertension, diabetes and hyperlipidemia. Pre-operative best corrected visual acuity (BCVA), refractive status, laterality of eye and biometry for intraocular lens implantation were noted. Operative note was reviewed for any complications during surgery in regards to IOL implantation.

Selected patients were followed up in specified intervals at 1 week, 4 weeks (1 month), 3 months, 6 months, 1 year and 2 years after surgery. Patients were assessed for visual acuity (Snellens and Log MAR) and slit lamp examination for corneal edema, iritis, Goldmann applanation tonometry and dilatation for implanted IOL status. The IOL stability parameters included IOL folds, decentration, posterior capsular opacification (and grading if present) and anterior capsular fibrosis. Patients with severe grade of PCO had Nd:YAG capsulotomy procedure performed on the same day. The total number of such procedures was noted down. Telephonic conversations were made to assure the compliance of the enrolled patients to the follow up schedule.

Statistical methods

Number of cases was calculated based upon statistical formula

$$n = \frac{p(1-p)\,Z^2}{E^2}$$

Considering 98% prevalence rate with 2.4% error of prevalence, the minimum sample size was 142 eyes. With 20% non-response rate, the number attained was 171. Consequently, 174 eyes of 114 patients were included in the study according to inclusion and exclusion criteria.

Data was collected with the help of a standard proforma designed for this study. All the data was entered in MS Excel. Coding and recoding was done in MS Excel. All the statistical analysis was done in SPSS 20. For continuous variables, Mean (SD) was calculated.

Results

Out of the total 174 eyes of 114 patients, 29 had only right eye (RE) operated, 25 had left eye (LE) operated and 60 patients had both eyes (BE) operated.

55 females (48.2%) and 59 males (51.8%) were included in this study (Figure 1). The age range was from 40 to 86 years (mean age 62.9 years, SD 11.2) with the mean (SD) age of females in the study being 62.3 (11.1) years and that of males was 63.4 (11.5) years.

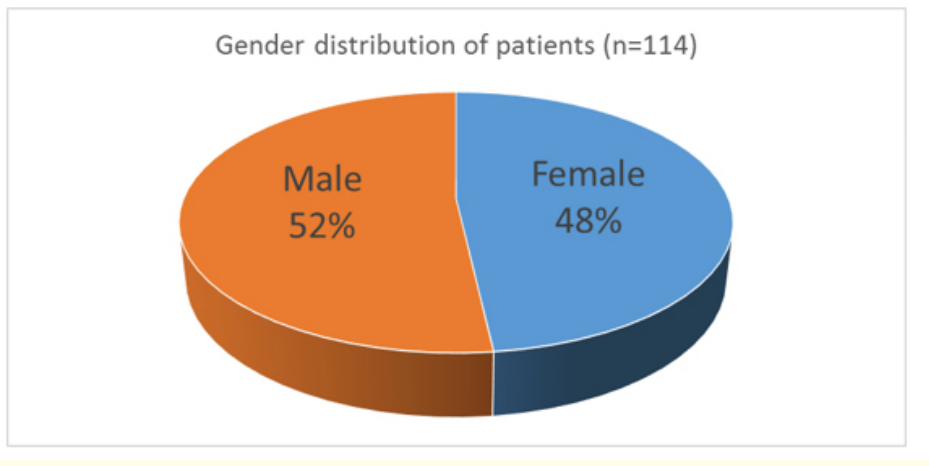

Figure 1: *Gender distribution.*

On the basis of literacy, maximum participants were illiterate 39 (34.2%) followed by secondary education in 34 (28.9%) (Table 1).

Literacy Status	Frequency	Percent
Illiterate	39	34.2
Literate	15	13.2
Primary	8	7.0
Secondary	34	29.8
Higher	18	15.8
Total	114	100

Table 1: *Literacy rate.*

On the basis of caste as per the socio demographic classification given in the population monograph of Nepal, 2014 [2], most of the patients belonged to Janajati and Hill caste 112 (98.3%) and minority belonged to Dalit and Madhesi castes (Table 2 and figure 2).

Seventy three (64.0%) of the patients had systemic diseases where 34 (29.8%) had diabetes mellitus, 59 (51.8%) had hypertension and 7 (6.1%) had hyperlipidemia (Table 3).

Ethnicity	Frequency	Percent
Dalit	1	0.9
Hill Caste	49	43.0
Janajati	63	55.3
Terai Madhesi Caste	1	0.9
Total	114	100

Table 2: *Ethnicity [2].*

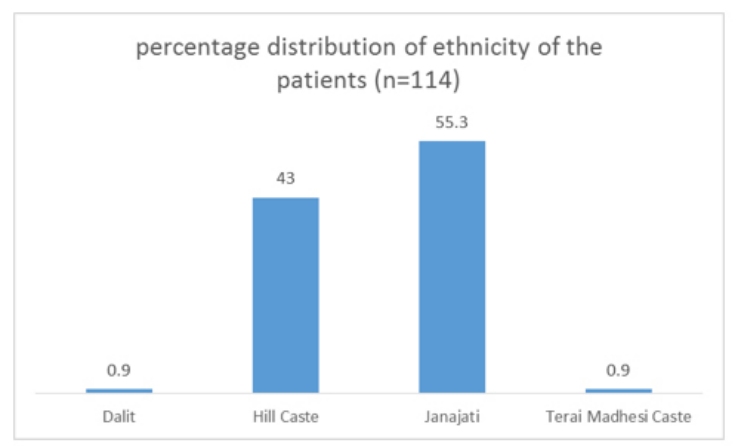

Figure 2: *Ethnicity.*

Systemic Disease	Frequency	Percent
No	41	36.0
Yes	73	64.0
Total	114	100.0
Diabetes Mellitus		
No	80	70.2
Yes	34	29.8
Hypertension		
No	55	48.2
Yes	59	51.8
Hyperlipidemia		
No	107	93.9
Yes	7	6.1

Table 3: *Presence of systemic diseases.*

A few other systemic diseases were noted in this study group. Two patients had Rheumatoid Arthritis, one patient had Chronic Obstructive Pulmonary Disease, two patients had Heart disease, one patient had Parkinsonism, one patient had hyperthyroidism and one patient was under medication for tuberculosis.

Vision Snellens (Log MAR)	Pre op BCVA		Post op 1 BCVA		1 week BCVA		4 week BCVA		3 months BCVA		6 months BCVA		2yr BCVA	
	N	%	n	%	n	%	n	%	n	%	N	%	n	%
6/6 - 6/18 (0.0- 0.5)	27	15.5%	125	71.8%	140	80.5%	168	96.6%	168	96.6%	167	96.0%	171	98.3%
< 6/18 - 6/60 (0.5-1.0)	76	43.7%	45	25.9%	33	19.0%	3	1.7%	2	1.1%	2	1.1%	3	1.7%
< 6/60 - 3/60 (1.0 - 1.5)	33	19.0%	4	2.3%	1	0.6%	1	0.6%	0	0.0%	1	0.6%	0	0.0%
< 3/60 - 1/60 (1.5 - 1.8)	28	16.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
< 1/60 < 1.9	7	4.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Missing	3	1.7%	0	0.0%	0	0.0%	2	1.1%	4	2.3%	4	2.3%	0	0.0%
Total	174	100.0%	174	100.0%	174	100.0%	174	100.0%	174	100.0%	174	100.0%	174	100.0%

Table 4: *Best corrected visual acuity (BCVA) chart: preoperative (at presentation) to 2 years postoperative.*

Post-operative complications

Anterior chamber reaction (iritis) was present in 19.0% in the 1st POD, 4.6% in a week, and 1.7% after a month (Table 5). No cases of severe iritis were reported whereas; moderate iritis was present in 1.7%, 0.6% and 0.6% in 1 day, 1-week and 1-month follow-up, respectively (Table 6).

Iritis	1 POD		1 Week		4 Week	
	Number	Percent	Number	Percent	Number	Percent
Yes	33	19.0	8	4.6	3	1.7
No	141	81.0	166	95.40	171	98.3
Total	174	100.0	174	100	174	100.0

Table 5: *Number/percentage of iritis.*

Iritis	1 POD		1 Week		4 Week	
	Number	Percent	Number	Percent	Number	Percent
Mild	30	17.2	7	4.0	2	1.2
Moderate	3	1.7	1	0.6	1	0.6

Table 6: *Severity of iritis.*

Corneal edema was noted in 8% of the eyes in the 1st POD while only in 0.6% after a month (Table 7 and figure 3).

Corneal Edema	1 POD		4 Week	
	Number	Percent	Number	Percent
No	160	92.0	173	99.4
Yes	14	8.0	1	0.6
Corneal Edema stages				
Early	8	4.6	1	0.6
Mild	6	3.4	0	0

Table 7: *Post-operative corneal edema.*

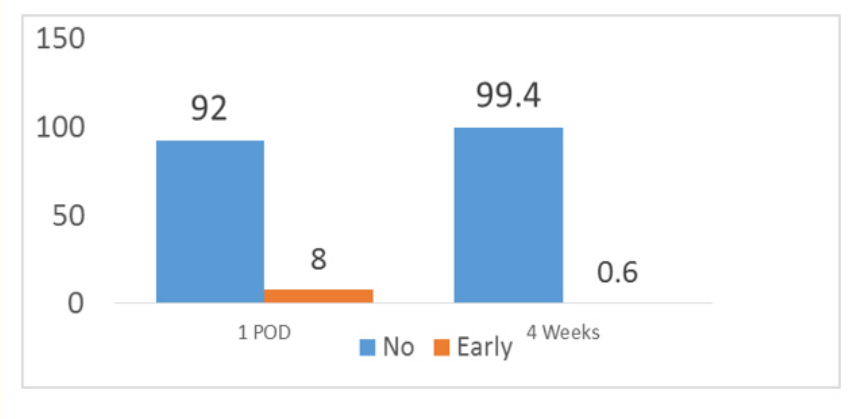

Figure 3: *Post-operative corneal edema.*

Three (1.7%) patients had high IOP on the first post operative day and it decreased to 1 (0.6%) in one week follow up (Table 8).

High IOP	POD 1 Day		One Week	
	Number	Percent	Number	Percent
No	171	98.3	173	99.4
Yes	3	1.7	1	0.6
Total	174	100	174	100

Table 8: *IOP rise after surgery.*

The incidence of posterior capsular opacification was recorded to be 6.3% of the eyes in the 3-month follow up. It increased to 7.0% in 6 months and 22.0% in 2 years. Most of the cases had mild opacification with grade I PCO accounting for 4.6% and 8.6% of total eyes in 6-month and 2-year follow-up. Similarly, Grade II PCO was present in 2.3% and 4.0% of the eyes respectively (Table 9).

No other post operative complications were noted to occur.

PCO	3 Months		6 Months		2 Years	
	Number	Valid Percent	Number	Valid Percent	Number	Valid Percent
No	163	93.7	162	93.1	152	87.4
Yes	11	6.3	12	6.9	22	12.6
Among PCO						
Grade 1	11(unspecified)	6.3	8	4.6	15	8.6
Grade 2			4.0	2.3	7	4.0

***Table 9**: Rates of PCO formation and grading.*

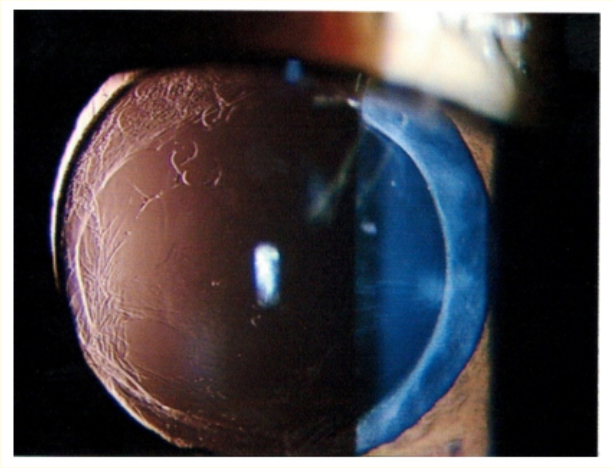

***Figure 4:** PCO Grade 1.*

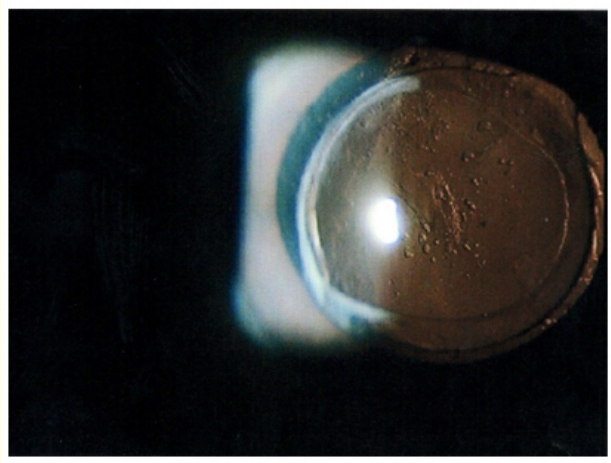

***Figure 5:** PCO Grade 2.*

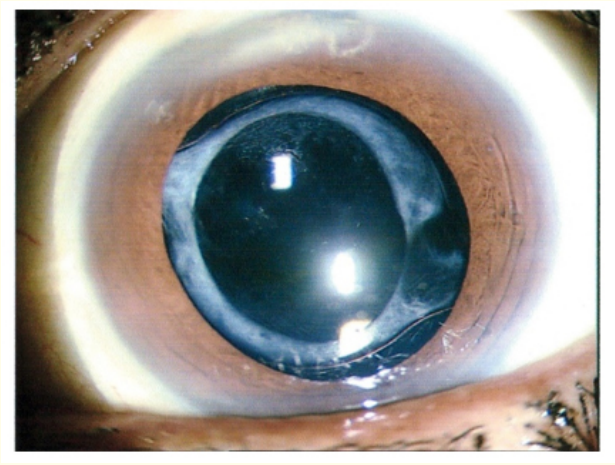

Figure 6: *Anterior capsular fibrosis.*

IOL-Related Complications

Folds in IOL were seen in 0.6% of the eyes in 6 months and 5.7% in 2 years (Table 10). No such folds were reported prior to 3-month follow-up.

IOL Folds	3 Months		6 Months		2 Years	
	Number	Percent	Number	Percent	Number	Percent
No	174	100.0	173	99.4	164	94.3
Yes	0	0.0	1	0.6	10	5.7
Total	174	100.0	174	100.0	174	100.0

Table 10*: Post-operative IOL folds.*

At the end of 2 years, 4% of the eyes were reported to have decentration of IOL (Table 11).

IOL Decentration 2 Years	Number	Percent
No	167	96.0
Yes	7	4.0
Total	174	100.0

Table 11: *Post-operative IOL decentration.*

None of the patient developed endophthalmitis.

Discussion

This study was conducted to study the safety and effectiveness of the Tecsoft Hydrophilic Acrylic Foldable Intraocular Lens, made by Fred Hollows Laboratories.

A previous study by Adhikari., *et al.* [3] using the same IOL, showed that the Tecsoft was suitable for use in children. Among 178 eyes of 120 children included in the study, 8 were below the age of 2 and 4 below 6 months of age. The final results of the study showed improved vision in 81% (Snellens BCVA 6/6-6/18). The benefit of the Tecsoft was the low cost as well as early visual rehabilitation to the patients which was critical in order to avoid amblyopia. Hence, Tecsoft hydrophilic IOL demonstrated safety and effectiveness in children, with very less post operative complications and less incidence of PCO.

Another study by Bajimaya., *et al.* [4] studied the outcome of implantation of Tecsoft IOL in 253 eyes of 172 patients for correction of aphakia after removal of cataractous lens in the adult population. This study found a definite positive impact with early visual rehabilitation of the patients without the need for spectacle correction for distance vision. Another prospective observational study by Gurung., *et al*. [5] showed that the Tecsoft foldable hydrophilic acrylic IOL used for Aphakia correction in children provided good visual outcome. The IOL could be easily and economically obtained in developing countries like Nepal and caused minimal intra and post-operative complications. Similarly, in a randomized single center comparative study for equivalence of 2 IOLs used in Cataract surgery by Constantinou., *et al.* in 2013 [6], the Tecsoft Flex IOL was found to be an economical alternative to other type of Foldable lens, therefore providing the benefit of early visual rehabilitation to the patient, and less complications and showed improved visual function with no difference with other type of lens. There was no difference in centration or stability among the Alcon Acrysoft lens and Fred Hollows Tecsoft lens. Also, there was no significant difference in the mean postoperative best corrected visual acuity at 1, 6 and 12 months in either group ($P < 0.05$).

In a study by Heiner., *et al*. they found a PCO formation rate of only 1% with the foldable enVistaMX60 IOL made of hydrophobic acrylic polymer [7], whereas in this study, the PCO formation rate was 12.6% (22 eyes) with the Tecsoft lens. In the previous comparative study by Constantinou., *et al*. the incidence of PCO was 16.2% and 13.2% at the end of 1 year in AcrySof and Tecsoft groups, respectively [6]. Slightly higher rates of PCO formation with Acrysof IOLs was also found by a retrospective study involving AcrySof IOLs with Nd:YAG capsulotomy rate of 17.3% (13 of 75 eyes) for the mono focal spherical group (Natural SN60AT; Alcon Laboratories, Inc.)and 4.0% (3 of 75 eyes) for the monofocal aspheric group(IQ SN60WF; Alcon Laboratories, Inc.). In that study, the mean time from surgery to Nd:YAG capsulotomy was 13.0 ± 9.3 months in the monofocal spherical group and 9.3 ± 6.4 months in the monofocal aspheric group [8].

In studies by Lorenz Vock., *et al*. in 2006 [9] and K A Becker., *et al.* also in 2006 [10], they demonstrated that the Centerflex showed excellent functional results, low values for endothelial cell loss and inflammatory signs, and no anterior capsule shrinkage. However, PCO formation was higher compared to other IOLs, which might have been due to the incomplete sharp edge at the optic-haptic junctions [9,10]. Therefore, the equivalent IOL to Tecsoft have excellent early visual recovery to the patient, however, higher PCO rate is owing to the IOL design.

Another study has shown that there is no significant difference in terms of PCO and Nd: YAG rates between one- and three-piece IOLs. The Tecsoft hydrophilic acrylic foldable IOL has a single piece design and has comparable PCO rates to others.

Postoperatively, patients with a hydrophobic IOL developed more glistening than those with the hydrophilic IOL [11].

Higher uveal biocompatibility has been noted with the modern hydrophilic acrylic IOLs than with the hydrophobic acrylic IOLs [12]. The Tecsoft is a Hydrophilic Acrylic IOL and there was less iritis (18.9% associated with it on the first postoperative day itself). The average rate of endophthalmitis after cataract surgery was approximately 0.023% as reported in a large study from 2006 - 2014 where 480,104 cataract surgeries was taken into account [13]. In our study of 174 eyes that underwent cataract surgery, no cases of endophthalmitis was reported. This further affirms uveal biocompatibility of Tecsoft IOL as there was neither infectious nor sterile endophthalmitis.

In terms of corneal edema as a marker for biocompatibility, in a study of 242 eyes with uncomplicated phacoemulsification surgery and insertion of a foldable acrylic lens Tecnis IOL (Abbott Medical Optics, Santa Ana, CA, USA), the rate of postoperative corneal edema was 4.5% in non-diabetics and 14.3% in diabetic subjects [14]. This was comparable to our study as the average rate of corneal edema in our study was 8% and as we had 29.8% diabetic subjects.

Conclusion

The Tecsoft Sterile Foldable Acylic Intraocular Lenses manufactured by The Fred Hollows Intraocular Lens Laboratory was found to be safe and effective in the primary visual rehabilitation immediately after uncomplicated Phacoemulsification surgery for cataract.

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