A Randomized, Single-Center Study of Equivalence of 2 Intraocular Lenses Used in Cataract Surgery

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Purpose: To compare the outcomes of 2 intraocular lenses (IOLs) for the treatment of age-related cataracts.

Design: Prospective, randomized trial.

Participants: Patients with age-related cataracts were recruited and randomized to receive phacoemulsification and implantation of either the AcrySof SA60AT lens (Alcon, Inc, Fort Worth, TX) or the low-cost Tecsoft Flex lens (Fred Hollows Foundation, Tilganga, Nepal). A total of 300 patients were available for description and analysis (148 in the AcrySof group and 152 in the Tecsoft group).

Methods: Patients underwent phacoemulsification and implantation of the AcrySof SA60AT lens or the Tecsoft Flex lens. They were followed up and examined at baseline, 1 week, 1 month, 6 months, and 12 months after cataract surgery.

Main Outcome Measures: Uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (BDVA), incidence of posterior capsule opacification (PCO), Visual Function Index questionnaire results, and safety of the implanted IOLs.

Results: No significant difference ($P>0.05$) was found in UDVA and BDVA after surgery between the 2 groups. The equivalence test of the 95% confidence intervals showed that both lenses had an equal improvement of UDVA and BDVA as well as similar rates of PCO after cataract surgery. There was no significant difference between the 2 groups with regard to visual functioning or the incidence of adverse surgical events during ($P>0.05$) or after ($P>0.05$) the surgery.

Conclusions: The Tecsoft Flex IOL is a low-cost suitable alternative that is similar to the AcrySof IOL in terms of safety and visual outcomes.

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article. *Ophthalmology 2013;120:482–488 © 2013 by the American Academy of Ophthalmology.*

Cataract is a major cause of reversible visual impairment in elderly persons within Australia and around the world.[1–7] In Australia, it is estimated that by the year 2021, the number of people affected by cataract will increase by 63%, consequently increasing the prevalence and burden of visual impairment.[8,9]

Vision impairment resulting from cataract can result in significant reduction in the visual functioning and quality of life of a patient. Specifically, patients may have difficulty in driving, reading, and performing other daily activities.[10] Cataract extraction with implantation of an intraocular lens (IOL) not only attempts to restore visual acuity, but also improves visual functioning, which can improve further patient self-reported quality of life.[10] Cataract surgery in the form of phacoemulsification and IOL implantation is the most frequently performed ophthalmic surgical procedure in Australia with few complications and arguably is the most cost-effective surgical procedure worldwide.[11–15] Over the years, several new materials and designs of IOLs have been developed and evaluated for their safety and efficacy. Modern foldable acrylic IOL materials are considered more biocompatible than the previously commonly implanted polymethyl methacrylate lenses.

The treatment for cataracts already accounts for a considerable proportion of vision-related Australian Medicare costs with a continuous increase in Medicare claims seen for cataract surgery over the last 2 decades.[16] A 2.6-fold increase in the total number of cataract procedures from 1985 through 1994 has been documented in Australia.[17] With the doubling in the rate of cataract surgery in the last 20 years,[16,17] further growth in the number of cataract surgeries required to meet an increasing cataract burden will affect future health care spending. Very little local clinical evidence exists to demonstrate the most cost-effective use of medical devices generally, and this applies particularly to the best use of IOLs.

The main objective of this prospective randomized study was to assess the safety, efficacy, and equivalence of 2 IOLs, the AcrySof SA60AT (Alcon, Inc, Fort Worth, TX) and the Tecsoft Flex lens (Fred Hollows Foundation,

ISSN 0161-6420/13/$–see front matter
http://dx.doi.org/10.1016/j.ophtha.2012.08.035

Tilganga, Nepal) in human eyes for the treatment of cataracts. The benefit from the 2 IOLs studied being possibly equivalent is that the very significantly cheaper Tecsoft Flex IOL could be used with confidence in cataract surgery with IOL implantation, saving the Australian community millions of dollars in health care spending.

Patients and Methods

Patient Selection

A prospective, randomized trial to determine the clinical efficacy and safety of the 2 IOLs, the AcrySof SA60AT IOL and the Tecsoft Flex IOL, was conducted in human eyes for the treatment of age-related cataracts. The study protocol followed the tenets of the Declaration of Helsinki and was approved by the Human Research Ethics Committee of the Royal Victorian Eye and Ear Hospital, Melbourne, Australia. The study trial is registered with the Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au/trial_view.aspx?ID=82414; accessed March 12, 2012).

All patients 40 years of age or older with uncomplicated age-related cataract who were willing to comply with the protocol and who provided informed consent were recruited from the Royal Victorian Eye and Ear Hospital Cataract Clinic (Melbourne, Australia). Written informed consent was obtained from all patients before the initiation of any study-related procedure. Patients were excluded from the study if they had a history or clinical signs suggestive of ocular inflammation, diabetic retinopathy, glaucoma, pseudoexfoliation, amblyopia, central corneal opacity, or Fuchs' endothelial dystrophy. Only IOLs within the power range of 19.5 to 22 diopters (D) were available during the study period.

On enrollment into the study, patients were allocated sequentially specific numbers. These patients were assigned randomly to receive cataract surgery with implantation of either: (1) the AcrySof IOL or (2) the Tecsoft Flex IOL. Each eye was randomized separately if the other eye was eligible to be included at the end of the 1-month postoperative visit of the first enrolled eye.

Intraocular Lenses

Two types of IOL were used in the study: the AcrySof SA60AT IOL and the Tecsoft Flex IOL. These IOLs have been approved for use by the Therapeutic Goods Administration, Australia. Both foldable single-piece ultraviolet-absorbing IOLs have an overall diameter of 13.0 mm and biconvex optics. The hydrophobic acrylic AcrySof SA60AT IOL has an optical diameter of 6.0 mm with a total length of 13.0 mm (A constant, 118.4; refractive index, 1.55). The Tecsoft Flex foldable IOL is a poly-HEMA (hydroxy ethyl methacrylate) acrylic lens with open-loop C haptics and a square edge (A constant, 118; refractive index, 1.461). The haptics are angulated at 5°. The optic diameter of the model used for this study is 5.9 mm and total IOL length is 13.0 mm. For the purpose of this study, each AcrySof IOL cost US$215, whereas the cost of the Tecsoft Flex IOL was US$17.

Surgical Technique

Before cataract surgery, all patients underwent standard ophthalmic examinations by the investigators. Biometry was performed before the operation with the use of the IOL Master (Zeiss, Version 5.0; Carl Zeiss Meditec Ltd, Jena, Germany) or an A-scan. All patients underwent phacoemulsification and IOL implantation using topical or local anesthesia and a standard surgical technique. All surgeries were performed by 2 experienced anterior segment surgeons (R.B.V. and V.J.). Patients or surgeons were not masked to the type of the IOL.

A 2.8-mm corneal incision was used for insertion of the AcrySof IOL (Monarch injector systems, Alcon, Fort Worth, TX), and a 2.8-mm incision was used for insertion of the Tecsoft Flex IOL (Hydro-glide and Hydro-shooter, Fred Hollows Foundation). The wounds were not sutured unless a leak was evident after hydration. After surgery, prednisolone acetate 1% and chloramphenicol 0.5% eye drops were prescribed 4 times daily for 1 week. Antibiotic eye drops were stopped after 1 week and corticosteroids were tapered over a period of 4 weeks after surgery.

Patient Evaluation

Patients were followed up and examined at baseline, 1 week, 1 month, 6 months, and 12 months after the surgery. At each follow-up, routine assessment included uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (BDVA) testing (Snellen decimal acuity), intraocular pressure (IOP), slit-lamp examination, and fundus evaluation. At the 1-, 6-, and 12-month follow-up visits, the pupil was dilated maximally and the posterior capsule was evaluated for any opacification (posterior capsule opacification [PCO]). Yttrium–aluminum–garnet capsulotomy was advised in cases with significant PCO in the visual axis on slit-lamp examination along with a drop of at least 1 line in the BDVA.

The Visual Function Index (VF-14), a 14-item instrument designed to measure visual function impairment in cataract patients,[18] was administered verbally before and after surgery. The questionnaire included 14 vision-dependent activities such as reading, writing, walking, sewing, cooking, playing, and driving. Higher scores represent better visual functioning (i.e., less difficulty), and therefore, greater ability in performing the activity. The 2 driving items were removed from the VF-14 to improve the scale validity for the test sample, and the short version was used for comparison.[19] Details about applying Rasch analysis to the questionnaires for this purpose have been described elsewhere.[20–22] In brief, for the Rasch analysis, item difficulty and patient ability were calibrated on the same scale and were expressed as scores (in logits). The Rasch analysis was performed using the Andrich rating scale model for multiple response options for an item in the Winsteps software version 3.68 (Winsteps.com, Beaverton, OR).[23]

Outcome Measures

The main objective of this study was to test the equivalence of 2 lenses (AcrySof IOL and Tecsoft Flex IOL) by means of distance visual acuity. The assessment of results was based on a comparison with the patient's preoperative condition (i.e., distance visual acuity), as well as an analysis of reported complications.

Sample Size

The trial was designed as an equivalence study. An a priori equivalence bound (±0.20 mean) was set to test the equivalence of the 2 lenses. An equivalence test was performed with EquivTest software version 2.0 (Statistical Solution Ltd, Saugues, MA). The study sample size was calculated using Stat Tools (http://www.stattools.net/index.php; accessed August 12, 2012). To test the equivalence of 2 lenses, a sample size of 154 eyes in each group yielded 76% power.

Statistical Analysis

Statistical tests were performed to compare baseline characteristics and adverse events between both groups. Normality of the vari-

ables was examined using boxplots, Kolmogorov-Smirnov tests, and Shapiro-Wilks tests. Continuous variables were presented as median (interquartile range [IQR]) for skewed distribution and mean (standard deviation) for normal distribution, whereas categorical variables were presented as absolute (n) and relative (%) frequencies. Differences in continuous variables between the 2 groups were evaluated by the Mann-Whitney *U* test for skewed distributed data and the *t* test for normally distributed data. In general, the chi-square test or, if necessary, the Fisher exact tests were used for categorical outcomes such as gender and adverse event rate. Two-sided tests were used at the significance level of 5%, and all analyses were performed using Stata software version 11.0 (Stata Corp, College Station, TX).

The trial was designed as an equivalence study, with a primary outcome of UDVA and BDVA. An a priori equivalence bound (±0.20 mean) was set to test the equivalence of 2 lenses. An equivalence test was performed with EquivTest software version 2.0.

Results

A total of 310 patients were recruited; 153 received the AcrySof IOL and 157 received the Tecsoft Flex IOL. Ten patients could not join the study, 5 in each of the groups. Thus for description and analysis, 300 patients were included (148 in the AcrySof IOL group and 152 in the Tecsoft Flex IOL group). In the Tecsoft Flex IOL group, 1 participant died before the 6-month follow-up (Fig 1).

The mean age of patients was 71.4±8.5 years in the AcrySof IOL group and 73.7±7.1 years in the Tecsoft Flex IOL group (P = 0.01). Women outnumbered men in both the AcrySof (n = 80; 54.1%) as well as the Tecsoft (n = 82; 54%) groups (P = 0.98). There were no differences in either group before surgery in terms of associated ocular diseases (P = 0.60). However, the number of diabetic patients was significantly higher in the AcrySof group as compared with the Tecsoft Flex group (26.4% vs. 15.8%; P = 0.03). Overall, hypertension was the most commonly associated systemic morbidity in both groups (Table 1, available at http://aaojournal.org).

Table 2 (available at http://aaojournal.org) presents the preoperative clinical characteristics in both groups. More than half of the patients had mixed cataracts. The types of cataract as well as preoperative biometric measurements were similar in both groups.

Table 3 (available at http://aaojournal.org) compares the characteristics of surgical procedures in both groups. Phacoemulsification could be completed in all cases. Superior corneal incision was used predominantly (60.7%), followed by a temporal corneal incision (39.3%). There was a significant difference between the 2 groups in terms of the site of the main incision during surgery (P = 0.02). A superior corneal incision was used more commonly for implantation of the Tecsoft Flex IOL, whereas a temporal corneal incision was used more often in the AcrySof IOL group.

Complications

There was no significant difference in the incidence of adverse surgical events during (P>0.05) or after (P>0.05) surgery

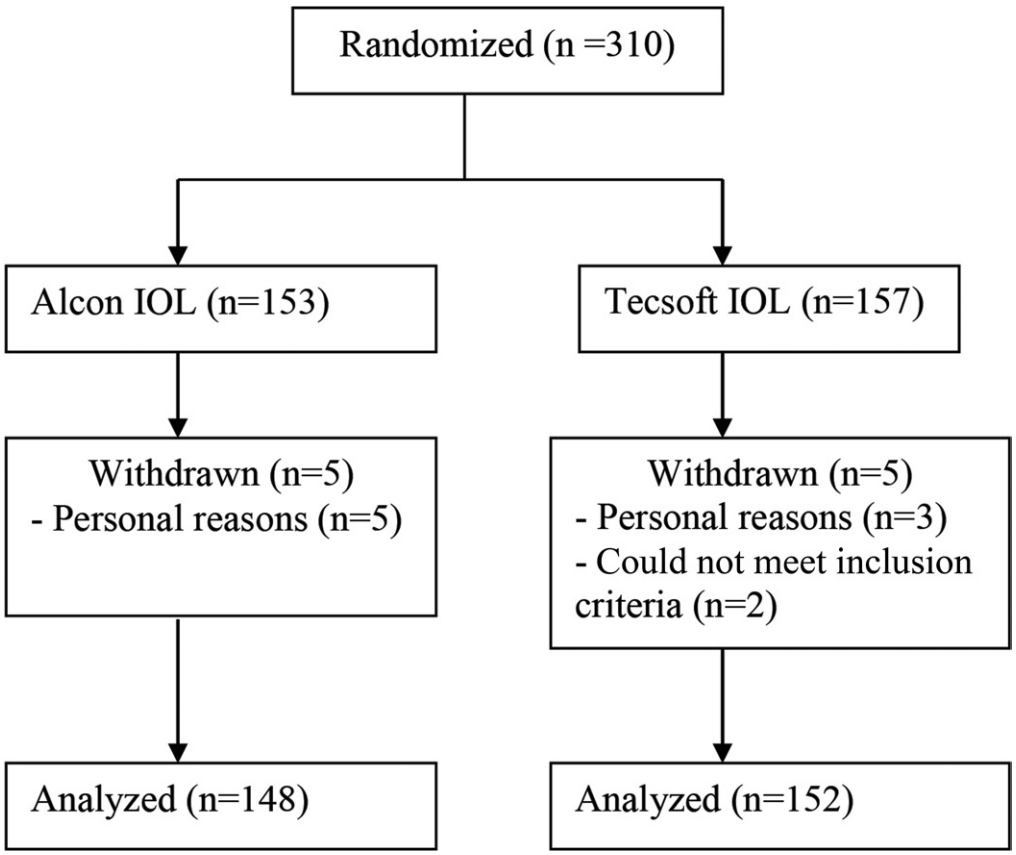

Figure 1. Flow chart showing the randomization of participants in the AcrySof (Alcon, Inc., Fort Worth, TX) and Tecsoft Flex (Fred Hollows Foundation, Tilganga, Nepal) intraocular lens (IOL) groups.

Table 4. Results of Uncorrected Distance Visual Acuity, Best-Corrected Distance Visual Acuity, Spherical Equivalent, and Intraocular Pressure at Baseline and 1, 6, and 12 Months after Surgery in the AcrySof and Tecsoft Intraocular Lens Groups

	Baseline		1 Month		6 Months		12 Months	
Factor	*AcrySof Lens*	*Tecsoft Flex Lens*	*AcrySof Lens*	*Tecsoft Flex Lens*	*AcrySof Lens*	*Tecsoft Flex Lens*	*AcrySof Lens*	*Tecsoft Flex Lens*
UDVA	0.25 (0.23)	0.21 (0.23)	0.63 (0.50)	0.63 (0.67)	0.90 (0.37)	0.63 (0.50)	1.0 (0.37)	0.80 (0.37)
P value	0.09		0.15		0.12		0.17	
BDVA	0.5 (0.33)	0.5 (0.38)	1.0 (0.20)	1.0 (0.20)	1.0 (0.20)	1.0 (0.20)	1.0 (0.20)	1.0 (0.20)
P value	0.60		0.64		0.36		0.24	
Median SE (IQR)	0.00 (2.25)	0.00 (2.93)	−0.38 (0.63)	−0.63 (0.75)	−0.38 (0.50)	−0.50 (0.75)	−0.25 (0.50)	−0.50 (0.63)
P value	0.99		<0.001		<0.001		<0.001	
IOP (SD), mmHg	15.5 (4.0)	15.0 (4.0)	15.0 (3.0)	14.0 (5.0)	15.0 (2.0)	14.0 (3.0)	15.0 (3.0)	15.0 (2.0)
P value	0.78		0.02		0.02		0.38	

BDVA = best-corrected distance visual acuity; IOP = intraocular pressure; IQR = interquartile range; SD = standard deviation; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.

(Table 3, available at http://aaojournal.org). No problems were encountered during implantation of IOL in any of the cases. Rupture of the posterior capsule occurred in 1 patient in the AcrySof IOL group. An anterior chamber IOL implantation was performed in this case. Zonular dialysis was observed during surgery in 1 patient in the Tecsoft Flex IOL group. One patient in the Tecsoft Flex IOL group required suturing of the main wound because of persistent leak. None of the cases in the 2 groups manifested an unusual inflammatory response in the early postoperative period. The postoperative course was uneventful in all the patients in both groups at the end of 1, 6, and 12 months ($P>0.05$). There were no problems specifically associated with centration or stability of the IOLs in either group.

Results of UDVA, BDVA, spherical equivalent (SE), and IOP at baseline and at 1, 6, and 12 months after surgery are summarized in Table 4. At presentation (baseline), the mean preoperative UDVA was 0.25 (6/24 Snellen)±0.23 in the AcrySof IOL group compared with 0.21 (6/30 Snellen)±0.23 in the Tecsoft Flex IOL group ($P = 0.09$). The mean preoperative BDVA was 0.50 (6/12 Snellen)±0.33 in the AcrySof IOL group compared with 0.50 (6/12 Snellen)±0.38 in the Tecsoft Flex IOL group ($P = 0.60$). There was no significant difference in the mean postoperative BDVA at 1, 6, and 12 months in either group ($P>0.05$).

The preoperative median SE was 0.00 D (IQR, 2.25 D) in the AcrySof group and 0.00 D (IQR, 2.93 D) in the Tecsoft group ($P = 0.99$). Before surgery, IOP was similar between both groups ($P = 0.78$). The median (IQR) 1-month SE was −0.38 D (0.63 D) in the AcrySof group and −0.63 D (0.75 D) in the Tecsoft group ($P\leq0.001$). The median SE decreased significantly to −0.25 D (0.50 D) and −0.50 D (0.63 D), respectively, at 12 months ($P\leq0.001$). The SE outcome at 1 month after surgery was within ±0.50 D for 66.2% of patients in the AcrySof group and 45.9% of patients in the Tecsoft group ($P<0.001$).

Changes in the UDVA, BDVA, mean SE, IOP, and VF-14 results at 1, 6, and 12 months after surgery are summarized in Table 5. There was no significant difference between the groups in UDVA and BDVA after surgery. However, the equivalence test of the 95% confidence intervals for the difference in UDVA and BDVA between the groups was significant, demonstrating that both lenses had an equal effect in improvement of UDVA and BDVA. No significant difference in SE or IOP was seen between the 2 groups or when SE or IOP were tested for equivalence.

The VF-14 quality of life questionnaires were completed by all patients. There was no significant difference in the results between the 2 groups before surgery ($P = 0.50$). The mean postoperative VF-14 scores were significantly higher than the preoperative scores in both groups, indicating a substantial improvement in visual functioning after surgery in both groups. Although a significant difference was observed between the groups at the end of 1, 6, and 12 months after surgery, the equivalence between the 2 lenses was significant before and after surgery ($P<0.05$), indicating that the IOLs were equivalent in terms of improvement of visual function after surgery.

On a subjective assessment, there was no significant difference in the posterior capsule status (folds or opacity) between the groups ($P>0.05$; Table 6). Furthermore, the equivalence test of the 95% confidence intervals for the difference in rates of PCO between the groups was significant, demonstrating that both lenses had an equal effect in the rates of PCO after cataract surgery.

Discussion

Cataract is the leading cause of blindness. Consequently, cataract surgery is one of the most commonly performed surgical procedures in ophthalmology. The World Health Organization predicts that an estimated 32 million cataract operations will be performed in the year 2020. This increase in volume of cataract surgery will be a consequence of an increased number of elderly people and also in part of a worldwide increase in provision of medical services.[24] The cost of cataract surgery varies in different parts of the world. In 2005, the mean total costs per cataract intervention in 9 European countries (Denmark, England, Hungary, Germany, The Netherlands, Poland, France, Italy, and Spain) were €714, ranging from €318 to €1078 (1€ = US$1.18 for 2005).[25] Cataract surgery, however, is less expensive in Europe compared with the United States, where the mean cost of cataract surgery totals US$2525.[26] The high cost of implantable prosthetic devices, including IOLs, has been discussed in Australia.[27] Brian and Taylor[28] commented that unless patients pay for their own surgery and subsidize that of those who cannot afford it, widespread cataract surgery will not be sustained. A suggested alternative approach is to develop a direct link between cataract services and revenue-generating industry. Manufacturing a low-cost IOL is an excellent example of this arrangement.[29,30] The Fred Hollows Foundation is an Australian nongovernment organization that has developed IOL manufacturing facili-

Table 5. Ninety-Five Percent Confidence Intervals and *P* Values for Equivalence Tests Comparing the Effect of the AcrySof Lens and Tecsoft Lens in Cataract Surgery

Factor	AcrySof Lens, Mean (Standard Deviation)	Tecsoft Flex Lens, Mean (Standard Deviation)	Difference, Means (95% Confidence Interval)	*P* Value*	*P* Value†
UDVA (Snellen) change after baseline (mos)					
1	0.46 (0.36)	0.40 (0.35)	0.07 (−0.01 to 0.15)	0.10	0.005
6	0.55 (0.29)	0.54 (0.31)	0.01 (−0.06 to 0.58)	0.77	0.001
12	0.57 (0.28)	0.57 (0.30)	0.004 (−0.06 to 0.07)	0.91	0.001
BDVA (Snellen) change after baseline (mos)					
1	0.57 (0.31)	0.57 (0.38)	0.004 (−0.07 to 0.08)	0.92	0.002
6	0.57 (0.30)	0.56 (0.34)	0.009 (−0.07 to 0.08)	0.81	<0.001
12	0.56 (0.28)	0.54 (0.34)	0.014 (−0.06 to 0.09)	0.68	<0.001
SE (diopters) change after baseline (mos)					
1	−0.125 (2.375)	−0.438 (3.250)	0.26 (−0.25 to 0.78)	0.12	0.18
6	−0.125 (2.313)	−0.375 (3.250)	0.15 (−0.36 to 0.66)	0.30	0.28
12	−0.125 (2.688)	−0.375 (3.250)	0.14 (−0.39 to 0.66)	0.34	0.30
IOP (mmHg) change after baseline (mos)					
1	−0.33 (3.10)	−1.09 (3.94)	0.75 (−0.05 to 1.56)	0.07	0.09
6	−1.30 (3.09)	−1.77 (3.68)	0.46 (−0.31 to 1.24)	0.24	0.30
12	−1.33 (3.16)	−1.37 (3.35)	0.03 (−0.73 to 0.80)	0.93	0.72
VF-14 (logits; mos)					
Baseline	2.36 (4.67)	2.72 (4.75)	−0.36 (−1.44 to 0.71)	0.50	0.037
1	9.09 (3.05)	8.18 (3.75)	0.91 (0.123 to 1.68)	0.02	0.003
6	11.4 (2.39)	10.70 (2.94)	0.71 (0.10 to 1.32)	0.02	<0.001
12	11.4 (2.30)	11.0 (2.60)	0.47 (−0.08 to 1.03)	0.09	<0.001

BDVA = best-corrected distance visual acuity; IOP = intraocular pressure; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; VF-14 = Visual Function Index.
*Difference between 2 groups.
†Equivalence of 2 groups. $P<0.05$ indicates 2 lenses are equivalent.

ties in Eritrea and Nepal.[31] Preliminary testing by several independent agencies (data not shown) confirmed that the IOLs manufactured by the Fred Hollows Foundation meet or exceed international regulatory standards for surface quality and optical resolution (Optical Quality Medical Device Testing, Germany), sterility and ethylene oxide residue testing (NATO Maintenance and Supply Agency), and mechanical testing in accordance with the ISO/DIS 11979-3 draft international standard (Lenstec, St. Petersburg, FL, and Optical Quality Medical Device Testing, Germany). The IOL laboratory also is certified by the Therapeutic Goods Administration, Woden, Canberra, Australia (http://www.fh-iol.com/news/8.html; accessed July 18, 2012). This randomized, comparative trial was planned to test the equivalence of 2 IOLs with same manufacturing specification, but with very different cost structures.

This study compared the performance of a low-cost foldable acrylic IOL manufactured by the Fred Hollows Foundation with another acrylic IOL, AcrySof IOL (Alcon), produced by one of the leading IOL manufacturers. Both

Table 6. Postoperative Status of the Posterior Capsule in AcrySof Lenses and Tecsoft Lenses after Cataract Surgery

Posterior Capsule Status	1 Month		6 Months		12 Months	
	AcrySof Lens	*Tecsoft Flex Lens*	*AcrySof Lens*	*Tecsoft Flex Lens*	*AcrySof Lens*	*Tecsoft Flex Lens*
Clear	136 (91.9)	144 (94.7)	130 (87.8)	138 (90.8)	123 (83.1)	131 (86.2)
Folds	4 (2.7)	0 (0.0)	1 (0.7)	2 (1.3)	1 (0.7)	1 (0.7)
Opacity	8 (5.4)	8 (5.3)	17 (11.5)	12 (7.9)	24 (16.2)	20 (13.2)
P value	0.12		0.50		0.76	
PCO	8 (5.4)	8 (5.3)	17 (11.5)	12 (7.9)	24 (16.2)	20 (13.2)
P value*	0.48		0.14		0.28	
P value†	<0.001		<0.001		<0.001	

PCO = posterior capsular opacification.
*Difference between 2 groups.
†Equivalence of 2 groups. $P<0.05$ indicates 2 lenses are equivalent.

IOLs compared well on all postoperative aspects, including UDVA, BDVA, and incidence of PCO, in the postoperative period. The incidence of intraoperative complications was acceptably low in both groups. There were no problems encountered during IOL insertion. The equivalence of both devices also was analyzed. An equivalence analysis is performed in an active control trial to demonstrate that the differences between any 2 treatments are not large in either direction. Both IOLs in the present study were found to be equivalent in terms of visual outcomes, rates of complications, and incidence of PCO by 12 months after surgery. Cataract surgery in both groups resulted in a substantial improvement in the VF-14 questionnaire scores.

Posterior capsular opacification is the most common complication of cataract surgery.[32] Decreased visual acuity induced by PCO is reported to occur in 20% to 40% of patients 2 to 5 years after surgery.[32] It has been well established that an acrylic lens is associated with a significantly reduced degree of PCO as compared with silicone or polymethyl methacrylate lenses.[33] In the present study, the incidence of PCO was 16.2% and 13.2% at the end of 1 year in AcrySof and Tecsoft groups, respectively. Although not statistically significant, the incidence of PCO in the Tecsoft group was lower than that in the AcrySof group at all follow-up points. Both IOLs were found to be comparable for PCO formation on equivalence analysis.

The level of functioning in patients after cataract surgery also was analyzed using the VF-14. The VF-14 is the one of the most extensively used measures of disability in patients with cataracts.[34] In earlier studies, patients showed large gains in functioning after cataract surgery with all versions of the VF-14.[10] Furthermore, the Rasch-scaled versions of the VF-14 were able to discriminate between visual functioning of preoperative and postoperative patients with much greater effect than the original Likert-scored version typified by first-generation instruments. The Rasch-based scoring has been shown to reduce standard errors and to increase measurement precision.[35] This method has been applied to the VF-14 in other studies and to other cataract-related questionnaires such as the Refractive Status and Vision Profile.[36,37] In this study, the mean VF-14 scores improved significantly in the postoperative period in both groups. Furthermore, equivalence analysis of VF-14 scores in the present study showed significant similarity between both IOLs.

The present study showed that the low-cost Tecsoft Flex IOL was effective for the management of age-related cataracts.[38] The efficacy of an IOL can be judged by the visual outcomes and performance over a consistent follow-up period. In the present study, UDVA and BDVA improved significantly compared with the preoperative level in both groups. During surgery, none of the complications was related to the IOL per se. No difficulties were encountered during insertion of a new type of IOL. It is noteworthy that the incidence of complications during and after the surgery was acceptably low in these patients up to a follow-up of 1 year after surgery. However, if these increased, the study sample does not have enough power to detect if they were clinically relevant. Further long-term postoperative follow-up data, especially for the incidence of PCO, would be desirable to comment on the safety of the new IOL.

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Footnotes and Financial Disclosures

Originally received: March 13, 2012.
Final revision: August 16, 2012.
Accepted: August 17, 2012.
Available online: December 1, 2012. Manuscript no. 2012-371.

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Presented as a poster at: American Academy of Ophthalmology Annual Meeting, October 2011, Orlando, Florida.

Financial Disclosure(s):
The author(s) have no proprietary or commercial interest in any materials discussed in this article.

Supported by an unrestricted grant from the HCF Foundation, Sydney, Australia; and BUPA, Hawthorn VIC, Australia. The sponsor had no role in the design or conduct of this research. The Centre for Eye Research Australia receives operational infrastructure support from the Victorian government.

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