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Postoperative Complications of True Dropless Cataract Surgery versus Standard Topical Drops

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Abstract

Purpose Compare postoperative outcomes in cataract surgery between eyes with standard drop regimen versus dropless protocol by residents.

Design Retrospective cohort study between April 1, 2018 and March 31, 2020.

Methods The study was performed at Lyndon B. Johnson General Hospital in Houston, Harris County, Texas. A total of 547 eyes (234 dropless vs. 313 standard) with phacoemulsification cataract surgery and minimum of 1-month follow-up with best-corrected visual acuity (BCVA) were included. Dropless received 40 mg sub-Tenon's triamcinolone and intracameral moxifloxacin. Patients were followed at postoperative day 1 (POD1), week 1 (POW1), and month 1 (POM1). Postoperative rate of BCVA better than 20/40 (Good vision) and rate of complications were compared between groups.

Results Good vision on POM1 in dropless (77.8%) was noninferior to standard (75.1%, $p = 0.80$). Complication rate in dropless (28.6%) was noninferior to standard (24.0%, $p = 0.13$). Intraocular pressure (IOP) elevation on POD1 ($p = 0.041$) and anterior chamber (AC) cells on POW1 and POM1 ($p < 0.001$) were more frequent in dropless. Mean spherical equivalent at POM1 was better in dropless (−0.37 D [±0.81 D]) compared with standard (−0.61D [±0.77 D], $p = 0.001$). Early posterior capsular opacification (early PCO) was more frequent in dropless ($p = 0.042$).

Conclusions Postoperative rate of BCVA better than 20/40 and rate of postoperative complications were noninferior, although dropless had higher rates of AC inflammation, IOP elevation, and early PCO.

Keywords
- dropless
- cataract surgery
- resident

Cataract is the leading cause of blindness worldwide in those 50 years of age and older.[1] Phacoemulsification cataract surgery is the standard of care to treat visually significant cataracts. Routine postoperative care includes topical corticosteroids and antibiotics. Given issues relating to postoperative topical drop use, including additional time taken to discuss postoperative drop regimen, patient adherence, incorrect installation, and corneal toxicity, there is interest in developing an effective dropless postoperative protocol.

Two of the major concerns after cataract surgery are infection and inflammation, for which topical antibiotics and topical corticosteroids are generally prescribed. The primary

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infection risk is endophthalmitis. It has been shown that combined intracameral antibiotics can help reduce the rate of endophthalmitis when compared with topical antibiotics alone.[2–4] This has led to the common practice of using both intraoperative intracameral and topical postoperative antibiotics. Similarly, topical postoperative corticosteroids reduce postoperative inflammation. The use of a subconjunctival[5–8] or sub-Tenon's intraoperative corticosteroid injection has been shown to be noninferior to postoperative topical corticosteroid drops in multiple studies.[9,10] However, one study demonstrated a transient increase in intraocular pressure (IOP) after subconjunctival corticosteroid injection.[6] Two studies compared a completely dropless protocol, subconjunctival triamcinolone, and intracameral antibiotics, to postoperative topical medication.[7,8] Neither study detected an increased risk of endophthalmitis, cystoid macular edema (CME), elevated IOP, or a difference in best-corrected visual acuity (BCVA).[7,8]

The dropless protocol at our institution was developed and implemented in response to a temporary reduced availability of topical prednisolone acetate for postoperative use in our safety net health care system. The purpose of this study was to compare the outcomes of uneventful resident-performed phacoemulsification cataract surgery (RPCS) with the dropless protocol compared with the standard protocol with the hypothesis that outcomes of the dropless protocol are noninferior to the standard protocol in RPCS.

Methods

This retrospective chart review was conducted at the Lyndon B. Johnson General Hospital (LBJ) of the Harris Health System in Houston, Texas. LBJ is an academic safety net hospital where a vast majority of cataract surgery is RPCS. Institutional review board (IRB) approval was prospective and obtained from The University of Texas Health Science Center Committee for the Protection of Human Subjects and the Harris Health System. The IRB approved a study for "Postoperative complications and cost-effectiveness after true dropless cataract surgery," although cost-effectiveness was not described here. All research adhered to the tenets of the Declaration of Helsinki and was Health Insurance Portability and Accountability Act compliant. The IRB (Committee for the Protection of Human Subjects) determined that informed consent was waived for this study. All categorizations in this study were reported using the data found in the patients' charts, a retrospective study.

Study Population

Charts of RPCS patients from April 1, 2018 to March 31, 2020 were reviewed. The study periods were divided in "March-to-March" time periods so that the postgraduate year 4 residents performing the surgeries had similar experience and training in the periods before and after the shortage. The lack of availability of prednisolone acetate drops was between March 2019 and October 2020, and the dropless protocol began at the start of the shortage. It was the primary method of RPCS throughout the remainder of the study period. Therefore, the ratio of eyes using dropless to standard protocol was not 1:1 throughout the study period, as a majority of the surgeries with the standard drop protocol occurred before March 2019. Patients were identified by CPT codes associated with cataract surgery (66982, 66984, 66940) with no other simultaneous operative codes. Eyes with less than 1-month follow-up or missing BCVA at month 1 visit were excluded. Eyes with preoperative conditions affecting postoperative visual acuity were excluded. Eyes with severe glaucoma were excluded based on perimetric measures based on the International Classification of Diseases 10th Revision coding. Intraoperative complications, posterior capsular rupture, retained lens material, vitreous prolapse, zonular dehiscence choroidal effusion, and hyphema were also excluded. If both eyes were otherwise eligible, the first eye was selected as the study eye.

Study Treatments

Eyes were categorized into either a dropless or standard group. After March 2019, most patients underwent cataract surgery using the dropless protocol in order to address the shortage. There was intermittent availability of prednisolone acetate 1% drops, and this availability, or lack thereof, was used to determine which protocol to use, regardless of attending surgeon. Eyes in the dropless group received 40 mg sub-Tenon's triamcinolone and 0.25 mg intracameral moxifloxacin, whereas eyes in the standard group received an identical dose of 0.25 mg intracameral moxifloxacin intraoperatively, topical prednisolone tapered over 4 to 6 weeks, and topical ofloxacin or moxifloxacin drops for 1 week.

Eyes that used an additional surgical device (trypan blue, Malyugin ring, miLOOP, capsular tension ring) intraoperatively were considered a complex surgery. Eyes with intraoperative complications were excluded as mentioned before.

Study Visits

Data were collected at the following visits: at the time of determination to perform cataract surgery (demographics and baseline ocular characteristics), operative day (complexity and drug administration), and postoperative scheduled visits on day 1 (POD1, 1–3 days), week 1 (POW1, 4 days–2 weeks), and month 1 (POM1, 3–6 weeks). Data collected at each scheduled postoperative visit were BCVA, IOP, presence of corneal edema, AC cell grades, presence of endophthalmitis, and presence of CME. Refraction was performed on POM1 only. If BCVA was not better than 20/30 at POM1, an optical coherence tomography (Heidelberg OCT) macula was performed. When there was more than one visit in the follow-up window, the visit closest to the 7- or 30-day visit was selected for the scheduled visit. Complications that occurred in any of the postoperative visits were recorded.

Measurements

IOP elevation was defined as an IOP spike greater than or equal to 10 mm Hg above baseline. CME was defined by presence of intra- or subretinal fluid and/or macular cysts on OCT. Persistent corneal edema was defined as corneal edema observed after 21 days. Other complications (e.g., corneal epithelial defect, Seidel positive wound, rebound/persistent inflammation, early posterior capsular opacification [early PCO, defined

as capsular opacification and/or cortical remnants identified postoperatively within 1 month]) were recorded, if noted in the chart.

Outcomes

The primary outcome measures were incidence of better than 20/40 BCVA at 1 month and incidence of postoperative complications. Secondary outcome variables were mean BCVA at 1 month and individual postoperative complications.

Sample Size Calculation

If the overall incidence of postoperative complications is assumed to be 25%, then the dropless protocol can be considered noninferior to the standard protocol as long as the dropless group does not have a 10% or higher rate of postoperative complications. A sample size of 257 cases was required in each group, with a statistical significance of 5 and 80% power.

Data Analysis

Data were summarized by mean (±standard deviation) and compared using two-sample *t*-tests for continuous variables or by frequency (%) and compared using the Fisher's exact test for discrete variables. Besides demographics and baseline characteristics, a one-tailed test was used to compare between groups. All statistical analyses were performed using SAS for Window v9.4 (SAS Inc, Cary, NC). A p-value <0.05 was considered statistically significant.

Results

In all, 1,149 eyes underwent RPCS from 914 patients and were reviewed. There were 547 (42.8%) eyes from 547 patients, including 234 (42.8%) patients in the dropless group and 313 (57.2%) patients in the standard group, eligible for analysis (►**Fig. 1**).

►**Table 1** shows the number of eyes in each group included in each study time period (April 1, 2018–March 19, 2019; March 20, 2019–October 31, 2019; and November 1, 2019–March 31, 2020). Before March 20, 2019, 207 of 209 eyes (99.0%) were using the standard drop protocol, whereas after the prednisone shortage started, the ratio of using the dropless protocol to the standard drop protocol (232:106) was about 2-to-1.

Demographics and Baseline Characteristics

Of these 547 patients, 175 (32.0%) were male. Most were Hispanic (335 [61.5%]), followed by Black (81 (14.9%]) and Asian (68 [12.5%]). The mean age at the time of surgery was 65.7 (±11.0) years. The mean age was 65.6 (±11.2) and 65.7 (±10.9) years for patients in the dropless group and standard group, respectively. No statistical differences in age ($p = 0.88$), sex ($p = 0.92$), race/ethnicity ($p = 0.17$), or medical

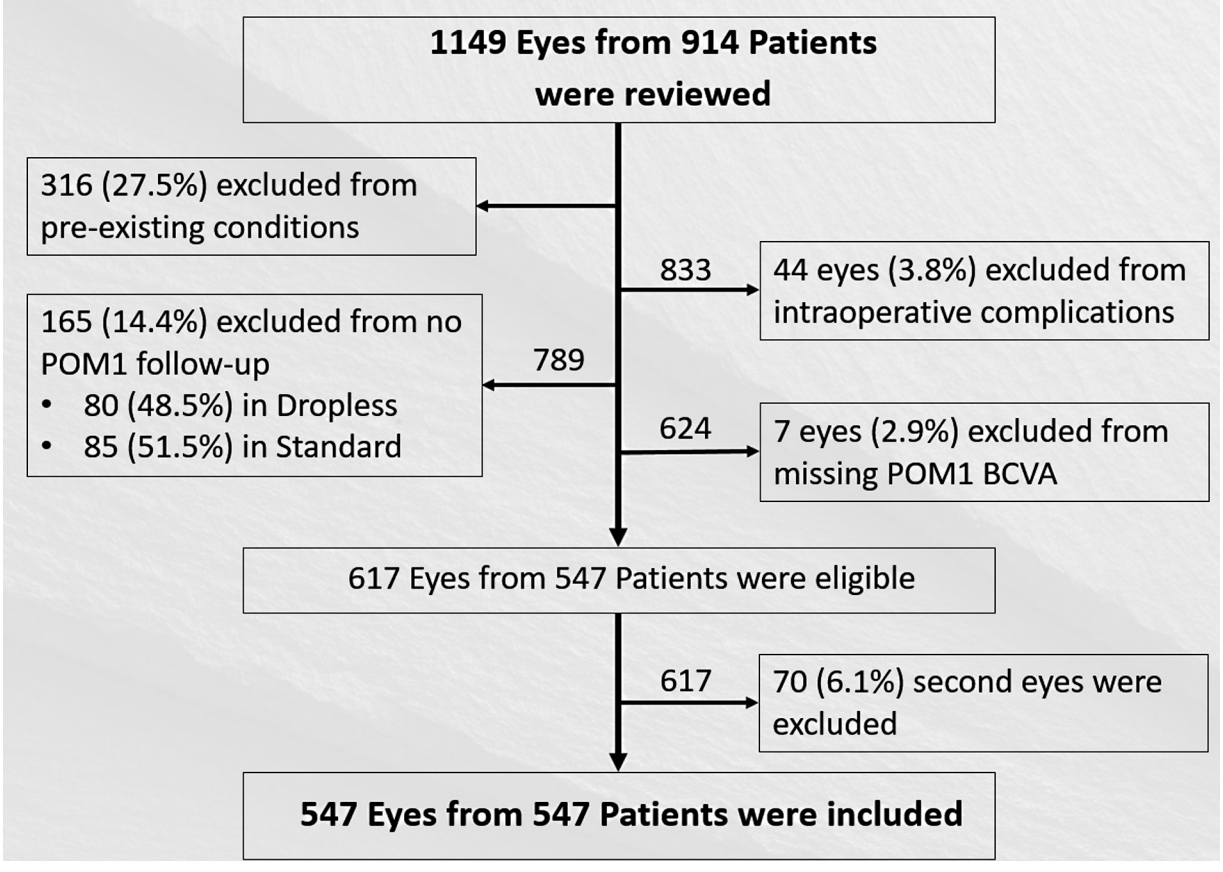

Fig. 1 Consort diagram of study population. BCVA, best-corrected visual acuity; POM1, postoperative month 1.

Table 1 Number of study eyes in each study time period

Group	Study time period			
	Between April 1, 2018 and March 19, 2019	Between March 20, 2019 and October 31, 2019	Between November 1, 2019 and March 31, 2020	Total
Dropless (%)	2 (1.0)	151 (66.5)	81 (72.0)	234
Standard (%)	207 (99.0)	76 (33.5)	30 (27.0)	313
Total	209	227	111	547

Table 2 Summary of demographics and medical comorbidity

	All patients ($N = 547$)	Dropless ($N = 234$)	Standard ($N = 313$)	p
Demographics				
Age (y [±SD])	65.7 (±11.0)	65.6 (±11.2)	65.7 (±10.9)	0.92
Sex (male, %)	175 (32.0)	74 (31.6)	101 (32.3)	0.93
Self-reported race/ethnicity (%)[a]				
White (%)	61 (11.2)	27 (11.5)	34 (10.9)	0.081
Black (%)	81 (14.9)	40 (17.1)	41 (13.2)	
Hispanics (%)	335 (61.5)	147 (62.8)	188 (60.5)	
Asian (%)	68 (12.5)	20 (8.6)	48 (15.4)	
Medical comorbidity				
Any systemic medical comorbidity (n, %)	295 (53.9)	129 (55.1)	166 (53.0)	0.66
Diabetes mellitus (n, %)	295 (53.9)	129 (55.1)	166 (53.0)	0.66
HbA1c from diabetes mellitus patients (unit [±SD])	7.71 (±1.58) [$n = 294$]	7.89 (±1.74) [$n = 128$]	7.57 (±1.43) [$n = 166$]	0.095
System diseases (n, %)	10 (1.8)	4 (1.7)	6 (1.9)	1.00

Abbreviation: SD, standard deviation.
[a]Missing two data points.

comorbidities ($p = 0.72$) were found between the two groups (►**Table 2**).

It should be noted that more than 50% of patients had diabetes mellitus (DM, 295 [53.9%]). The mean HbA1c for these DM patients was 7.71% (±1.58). The mean difference in HbA1c in DM patients was higher in the dropless group (7.89% [±1.74]) than in the standard group (7.57% [±1.43]). However, the difference was not statistically different ($p = 0.095$).

The baseline ocular characteristics are summarized in ►**Table 3**. The mean BCVA was 0.89 logMAR (±0.73, ~20/155). There was no statistical difference in mean BCVA between the groups, 0.93 logMAR (±0.73, ~20/170) in the dropless group and 0.86 logMAR (±0.73, ~20/145) in the standard group ($p = 0.25$). Although the percentage of glaucoma or glaucoma suspect ($p = 0.24$) and mean baseline IOP ($p = 0.71$) were not significantly different between the two groups, the number of the eyes on IOP-lowering medications in the standard group (28 [9%]) was significantly higher than the dropless group (4 [1.7%], $p < 0.001$). In total, 67 (12.3%) eyes had nonproliferative diabetic retinopathy and were not significantly different between both groups ($p = 1.00$). There were 28 (5.1%) white cataracts with 12 (5.1%) in the dropless group and 16 (5.1%) in the standard group ($p = 1.00$). Forty-six (19.7%) and 68 (21.7%) eyes had dense (4+) nuclear sclerotic cataracts in the dropless and in the standard groups, respectively. The cataract grades for each type of cataract were similar between the two groups ($p = 0.40$ for nuclear sclerotic, $p = 0.87$ for cortical, and $p = 0.078$ for posterior subcapsular).

Intraoperative Complexity

Nearly half of the study eyes (254 [46.4%]) required one or more intraoperative assistive devices. The most common device used was trypan blue (225 [41.1%]). There was no difference between the two groups in the overall use of intraoperative assistive devices ($p = 0.67$) or of individual devices ($p = 0.73$ for trypan blue, $p = 0.22$ for Malyugin, and $p = 0.14$ for capsular tension ring), except for the use of the miLOOP. A miLOOP was used in 12 (5.2%) eyes in the dropless and 3 (1.0%) eyes in the standard group ($p = 0.006$; ►**Table 3**).

Outcomes

The outcomes are summarized in ►**Tables 4** and **5**. Individual outcomes are summarized as follows.

Table 3 Summary of baseline ocular characteristics and intraoperative complexity

	All ($N = 547$)	Dropless ($N = 234$)	Standard ($N = 313$)	*p*
Eye (right, %)	271 (49.5)	117 (50.0)	159 (50.8)	0.86
Best-corrected visual acuity (logMAR [±SD])	0.89 (±0.73)	0.93 (±0.73)	0.86 (±0.73)	0.25
Ocular comorbidity				
Glaucoma and glaucoma suspect (*n*, %)	52 (9.5)	18 (7.7)	34 (10.9)	0.24
Intraocular pressure (mm Hg [±SD])	14.6 (±3.1) [$n = 517$]	14.5 (±3.0) [$n = 217$]	14.6 (±3.1) [$n = 300$]	0.71
Intraocular pressure-lowering medications (*n*, %)	34 (5.5)	4 (1.7)	28 (9.0)	<0.001
Nonproliferative diabetic retinopathy (*n*, %)[a]	67 (12.3)	29 (12.4)	38 (12.2)	1.00
Type of cataract				
White (*n*, %)	28 (5.1)	12 (5.1)	16 (5.1)	1.00
Nuclear sclerotic (*n*, %)				0.40
Mild (0–1 +)	83 (15.2)	41 (17.5)	42 (13.4)	
Moderate (2 + –3 +) (%)	350 (64.0)	147 (62.8)	203 (64.9)	
Dense (4 +) (%)	114 (20.8)	46 (19.7)	68 (21.7)	
Cortical (*n*, %)				0.87
Mild (0–1 +) (%)	338 (61.8)	145 (62.0)	193 (61.7)	
Moderate (2 + –3 +) (%)	152 (27.8)	63 (26.9)	89 (28.4)	
Dense (4 +) (%)	57 (10.4)	26 (11.1)	31 (9.9)	
Posterior subcapsular (*n*, %)[a]				0.078
Mild (0–1 +) (%)	343 (62.7)	142 (60.7)	201 (64.2)	
Moderate (2 + –3 +) (%)	158 (28.9)	65 (27.8)	93 (29.7)	
Dense (4 +) (%)	46 (8.4)	27 (11.5)	19 (6.1)	
Pseudoexfoliative material lens (*n*, %)	7 (1.3)	2 (0.9)	5 (1.6)	0.70
Phacodonesis/zonular loss (*n*, %)	0 (0)	0 (0)	0 (0)	n/a
Complex cataract surgery (*n*, %)	254 (46.4)	106 (45.3)	148 (47.3)	0.67
Intraoperative device(s) use				
Trypan blue (*n*, %)	225 (41.1)	94 (40.2)	131 (41.9)	0.73
Malyugin (*n*, %)	34 (6.2)	11 (4.7)	23 (7.4)	0.22
Capsular tension ring (*n*, %)	7 (1.3)	5 (2.1)	2 (0.6)	0.14
miLOOP (*n*, %)	15 (2.7)	12 (5.1)	3 (1.0)	0.006

Abbreviations: n/a, not available; SD, standard deviation.
[a]Missing one data point.

Best-Corrected Visual Acuity and Refraction

In all, 417 (76.2%) eyes had BCVA better than 20/40 at POM1 (182 (77.8%) eyes in the dropless group and 235 [75.1%] in the standard group). The rate of better than 20/40 BCVA in the dropless group was noninferior compared with the standard group at any time postoperatively ($p = 0.61$ at POD1, $p = 0.81$ at POW1, and $p = 0.80$ at POM1). Additionally, the mean BCVA was 0.15 (±0.20, ~20/30) at POM1. The dropless group was noninferior to the standard group in mean BCVA at any time postoperatively ($p = 0.54$ at POD1, $p = 0.39$ at POW1, and $p = 0.85$ at POM1; ►**Table 4**). Spherical equivalent (=sphere + cylinder/2) at POM1 was −0.37 D (±0.81) in the dropless group that was about a quarter diopter greater than the standard group (−0.61 D [±0.21], $p = 0.001$).

Follow-up Exams

There were no recorded cases of endophthalmitis during the study period (►**Table 4**). In all, 519 (95.6%) corneal edema was recorded on POD1 and reduced to 141 (25.9%) at POM1. The rate of corneal edema in the dropless group was noninferior to the standard group during the study period ($p = 0.38$ at POD1, $p = 0.46$ at POW1, and $p = 0.56$ at POM1). Similarly, 446 eyes (82.3%) had some anterior chamber (AC) cells (trace–4 +), the number reduced to 340 eyes (63.2%) at POW1 and further reduced to 150 eyes (27.5%) at POM1. On POW1 and POM1, the dropless group had a higher rate of AC cells ($p < 0.001$).

The mean IOP was approximately 1 mm Hg higher in the dropless group on POD1 ($p = 0.008$) and POW1 ($p = 0.001$),

Table 4 Summary of ocular exam during scheduled follow-up

	All eyes	Dropless eyes	Standard eyes	*p*
Postoperative day 1				
Visual acuity >20/40 (*n*, %)	235/541 (43.4)	101/230 (43.9)	134/311 (43.1)	0.61
Best-corrected visual acuity (logMAR [±SD])	0.43 (±0.46) [*n* = 541]	0.43 (±0.46) [*n* = 230]	0.43 (±0.46) [*n* = 311]	0.54
Corneal edema (*n*, %)	519/543 (95.6)	223/232 (96.1)	296/311 (95.2)	0.38
Anterior chamber cells (trace–4 + , %)	446/542 (82.3)	190/231 (82.3)	256/311 (82.3)	0.55
Anterior chamber flare (trace–4 + , %)	1/539 (0.2)	1/228 (0.4)	0/311 (0)	0.42
Endophthalmitis (*n*, %)	0/520 (0)	0/227 (0)	0/293 (0)	n/a
Intraocular pressure elevation (*n*, %)	49/457 (10.7)	26/185 (14.1)	23/272 (8.5)	0.041
Intraocular pressure (mm Hg [±SD])	17.9 (±5.0) [*n* = 483]	18.5 (±5.0) [*n* = 201]	17.4 (±4.9) [*n* = 282]	0.008
Cystoid macular edema (*n*, %)	0/545 (0)	0/232 (0)	0/313 (0)	n/a
Postoperative week 1				
Visual acuity >20/40 (*n*, %)	361/540 (66.9)	158/230 (68.7)	203/310 (65.5)	0.81
Best-corrected visual acuity (logMAR [±SD])	0.23 (±0.32) [*n* = 540]	0.24 (±0.37) [*n* = 230]	0.23 (±0.28) [*n* = 310]	0.39
Corneal edema (*n*, %)	388/540 (71.9)	167/231 (72.3)	221/309 (71.5)	0.46
Anterior chamber cells (trace–4 + , %)	340/538 (63.2)	175/229 (76.4)	165/309 (53.4)	<0.001
Anterior chamber flare (trace–4 + , %)	2/539 (0.4)	2/230 (0.9)	0/309 (0)	0.18
Endophthalmitis (*n*, %)	0/540 (0)	0/231 (0)	0/309 (0)	n/a
Intraocular elevation (*n*, %)	5/473 (1.1)	2/188 (1.1)	3/285 (1.1)	0.66
Intraocular pressure (mm Hg [±SD])	14.4 (±3.6) [*n* = 500]	15.0 (±3.4) [*n* = 202]	13.9 (±3.6) [*n* = 298]	<0.001
Cystoid macular edema (*n*, %)	5/540 (0.9)	1/231 (0.4)	4/309 (1.3)	0.94
Postoperative month 1				
Visual acuity >20/40 (*n*, %)	417/547 (76.2)	182/234 (77.8)	235/313 (75.1)	0.80
Best-corrected visual acuity (logMAR [±SD])	0.15 (±0.20) [*n* = 547]	0.14 (±0.19) [*n* = 234]	0.16 (±0.21) [*n* = 313]	0.85
Spherical equivalent (D [±SD])	−0.51 (±0.79) [*n* = 420]	−0.37 (±0.81) [*n* = 173]	−0.61 (±0.77) [*n* = 247]	0.001
Corneal edema (*n*, %)	141/545 (25.9)	60/233 (25.8)	81/312 (26.0)	0.56
Anterior chamber cells (trace–4 + , %)	150/546 (27.5)	85/234 (35.8)	65/312 (20.8)	<0.001
Anterior chamber flare (trace–4 + , %)	1/546 (0.2)	1/234 (0.4)	0/312 (0)	0.43
Endophthalmitis (*n*, %)	0/546 (0)	0/229 (0)	0/292 (0)	n/a
Intraocular pressure elevation (*n*, %)	3/502 (0.6)	3/210 (1.4)	0/292 (0)	0.073
Intraocular pressure (mm Hg [±SD])	14.1 (±3.6) [*n* = 530]	14.3 (±3.8) [*n* = 226]	13.9 (±3.4) [*n* = 304]	0.12
Cystoid macular edema (*n*, %)	53/547 (9.7)	26/234 (11.1)	27/313 (8.6)	0.20

Abbreviations: n/a, not available; SD, standard deviation.

but the difference in mean IOP was resolved by POM1 ($p = 0.12$). On POD1, 49 eyes (10.7%) experienced IOP elevation, which was reduced to 5 eyes (1.1%) at POW1 and 3 eyes (0.6%) at POM1. The incidence of IOP elevation on POD1 was significantly higher in the dropless group (26 [14.1%]) compared with the standard group (23 [8.5%]), $p = 0.041$). No incidence of CME on POD1 and the incidence increased to 5 eyes (0.9%) on POW1, then it further increased to 53 eyes (9.7%). The incidence of CME in the dropless group was noninferior to the standard group at POM1 ($p = 0.20$).

Complications

In total, 142 eyes (26.0%) experienced one or more postoperative complications. The rate of postoperative complication was 28.6% in the dropless group, which was noninferior to the standard group (24.0%, $p = 0.13$). The complications in

Table 5 Postoperative complications

Postoperative complication	All ($N = 547$)	Dropless ($N = 234$)	Standard ($N = 313$)	p
Posterior capsular opacification (n, %)[a]	9 (1.7)	7 (3.0)	2 (0.6)	0.036
Eyes with postoperative complication(s) (n, %)	142 (26.0)	67 (28.6)	75 (24.0)	0.13
Cystoid macular edema[b] (%)	60 (11.0)	29 (12.4)	31 (9.9)	0.22
Persistent corneal edema (%)	13 (2.4)	3 (1.3)	10 (3.2)	0.96
Corneal epithelial defect (%)	5 (0.9)	4 (1.7)	1 (0.3)	0.11
Intraocular pressure elevation[c] (%)	52 (9.5)	28 (12.0)	24 (7.7)	0.061
Seidel positive wound (%)	9 (1.7)	2 (0.9)	7 (2.2)	0.95
Persistent/rebound inflammation (%)	9 (1.7)	4 (1.7)	5 (1.6)	0.59
Others (%)	10 (1.8)	4 (1.7)	6 (1.9)	0.69
Number of complications (%)				
0 (%)	405 (74.0)	167 (71.4)	238 (76.0)	0.30
1(%)	127 (23.2)	61 (26.1)	66 (21.1)	
2 (%)	14 (2.6)	5 (2.1)	9 (2.9)	
3 (%)	1 (0.2)	1 (0.4)	0 (0)	

[a]Posterior capsular opacification is listed but is not counted toward the eye with postoperative complications.
[b]Cystoid macular edema includes CME only ($n = 54$), CME versus diabetic retinopathy ($n = 5$), CME versus epiretinal membrane ($n = 1$).
[c]Intraocular pressure elevation defined as intraocular pressure increased 10 mm Hg or more from baseline intraocular pressure (with and without medication treatment).

order from most to least frequent were CME (60 [11.0%]), IOP elevation (52 [9.6%]), persistent corneal edema (13 [2.4%]), persistent/rebounded inflammation (9 [1.7%]), Seidel positive wound (9 [1.7%]), and corneal epithelial defects (5 [0.9%]). The dropless group was noninferior to the standard group in these individual complications ($p = 0.22$ for CME, $p = 0.061$ for IOP elevation, $p = 0.96$ for persistent corneal edema, $p = 0.59$ for persistent/rebounded inflammation, $p = 0.95$ for Seidel positive wound, and $p = 0.11$ for corneal epithelial defects). Although not statistically significant, the incidence of IOP elevations had an uptrend in the dropless group (28 [12.0%]) compared with the standard group (24 [7.7%]).

Of 60 eyes that developed CME, 36 eyes (60%) had underlying DM. The average HbA1C in these diabetic patients who developed CME was 8.2% (±1.5) in the dropless group ($n = 19$) and 7.6% (±1.3) in the standard group ($n = 17$, $p = 0.14$ one-tail test).

Early PCO occurred in 9 eyes (1.7%) and was significantly higher in the dropless group (7 [3.0%]) compared with the standard group (2 [0.6%], $p = 0.036$; ►**Table 5**).

Discussion

To the best of our knowledge (PubMed search on April 27, 2022, using combined terms: ("injection" or "dropless") and ("triamcinolone" or "steroid") and "cataract" and ("postoperative" or "after") or ("dropless" and "cataract" and "surgery") between January 2012 and April 2022), this is the first study comparing the differences in postoperative BCVA and complications between a completely dropless protocol and standard postoperative drops on RPCS in a safety net setting.

The time period for the control population (April 2018–mid-March 2019) was chosen to match proportionately to the volume of surgical experience the residents had in the dropless protocol group time period. For example, surgical skills are quite different in July than in June of the senior residency year.

Our study population's poor baseline visual acuity and high rate of dense cataracts is likely a result of the relatively high comorbidity rate and barriers to accessing medical care. Our study's DM rate was 53.9%, which is more than two times the U.S. 2018 DM prevalence rate of 26.8% for those 65 years of age or older.[11] Patients with DM are five times more likely to develop cataracts compared with the general population.[12,13] The prevalence of comorbidities in low socioeconomic populations are not only greater than in the general population but also more likely to go untreated for longer periods of time due to barriers to access to care.[14] A cross-sectional, population-based study of Hispanic individuals demonstrated that language and financial barriers impede access to cataract surgery and suggested the barriers resulted in more severe visual impairment on initial presentation.[15] The results of the current paper are generalizable to similar populations.

Best-Corrected Visual Acuity

There were no statistically significant differences in visual outcomes between the two groups at any point. The percentage of patients reaching better than 20/40 vision at POM1 was 77.3% (117/229) in the dropless group and 75.1% (220/293) in the standard group ($p = 0.75$). Studies have shown that there are no differences in the proportion of

individuals who reached 20/40 vision or better postphacoemulsification cataract surgery between patients with mild to moderate diabetic retinopathy and unaffected individuals.[16] However, our percentage of all patients reaching better than 20/40 vision at POM1 is 76.1% (397/522), which is lower than those reported elsewhere.[17] This low percentage may be a result of this study's high rate of CME at POM1 (9.4% [49/522]), as poorer visual outcomes in patients with diabetic retinopathy are typically only seen if clinically significant CME is identified after surgery.[16,18] This may help explain that our proportionally poorer overall postoperative visual acuity rates were because of our relatively high rates of CME, rather than preoperative disease affecting baseline acuity. It should be mentioned that undiagnosed preoperative cases of diabetic macular edema due to obscuring thick cataracts may have affected postoperative visual outcomes, rather than genuine postoperative CME development.

Complication Rate

The dropless group did not have a higher rate of overall postoperative complications compared with the standard group ($p = 0.12$). Comparison of postoperative complications discussed in prior studies within the aforementioned PubMed search primarily included CME, AC inflammation, and IOP elevation. There were, however, no similar studies in our PubMed search that compared persistent corneal edema, early PCO, Corneal Epithelial Defect, Seidel positive wound, and persistent/rebound inflammation. Our results suggest that the dropless protocol is noninferior to the standard group with respect to the overall rate of postoperative complications, including those we have no current comparison for, except for early PCO.

Cystoid Macular Edema

The rate of developing CME postoperatively was noninferior in the dropless group (12.2%) compared with the standard group (9.6%, $p = 0.20$). Optical coherence tomography (OCT) identified CME rates in the literature range from 4 to 11%.[19,20] Our patient's relatively higher rates of CME may be explained by the high percentage of diabetics, as poor glycemic control (average HbA1c was 8.2 and 7.6% for the dropless group and standard group, respectively) is known to be a risk factor for CME.[21] The lack of difference in CME between groups confirms previous reports.[7,8] Rattan et al reported no differences in central macular thickness postoperatively when comparing topical moxifloxacin and dexamethasone versus intracameral moxifloxacin and subconjunctival triamcinolone.[7] Additionally, Lindholm et al showed that central retinal thickness was significantly thinner in the dropless group at POW1, POM1, and POM3 and suggest that subconjunctival triamcinolone injection is noninferior to dexamethasone drops and may be more sustainable and better in controlling pseudophakic CME.[8] This is also different from the current study, as we evaluated prednisolone acetate rather than dexamethasone drops.

We did not define clinically significant macular edema (CSME), associated with decreased visual acuity) for this study, but other similar studies have compared differences in CSME rather than OCT documented CME. A noncomparative, prospective study by Bardoloi et al of 200 eyes administering 0.1 mL each of moxifloxacin (500 mg) and triamcinolone acetonide (4 mg) were injected transzonularly reported no CSME, 7% of their patients had DM.[22] Additionally, Nassiri et al, an attending-performed retrospective longitudinal comparative study with 1,195 eyes, which used a 0.2 mL triamcinolone acetonide–moxifloxacin pars plana intravitreal injection, had no significant differences in CSME between their dropless and standard groups at 1 month.[23]

Anterior Chamber Cells

The presence of AC cells was higher in the dropless group at POW1 ($p < 0.001$) and POM1 ($p < 0.001$). This was not clinically significant and did not result in worse visual acuity. This differs from a randomized clinical trial of 1,000 eyes that administered intracameral moxifloxacin and subconjunctival triamcinolone, which reported lower frequency of AC cells in the dropless group on POD1 ($p = 0.03$) but no differences on later visits.[7] Additionally, Nassiri et al reported no differences in AC cells on POD1, with less residual AC cells in their dropless group at POW1 and POM1.[23]

Compared with other studies, it is likely that greater phacoemulsification energy was used at our hospital due to surgeons in training and the high number of mature lenses in this county population, possibly resulting in more postoperative inflammation. However, given that the cataract grades showed no statistical differences and the relative resident experience level remained steady with March-to-March collection periods, this increase in postoperative inflammation should be more or less controlled in our study—and we would expect no differences in AC cell presence. Instead, we found more inflammation in the dropless group, a difference that is likely attributed to the higher number of patients using a miLOOP in the dropless group ($p = 0.006$). Throughout the whole study period, miLOOP was introduced at our hospital and surgeons were being certified in its use. The frequency of use after certification decreased. It is possible that this difference indicates that there were more mature lenses in the dropless group requiring more energy, resulting in the higher AC cell inflammation postoperatively on POW1 and POM1 compared with the standard group.

Intraocular Pressure

Mean IOP was significantly higher in the dropless group at POD1 and POW1, and there was also significantly more IOP elevation in the dropless group at POD1. The mean IOP differences are small (<1.5 mm Hg) and not clinically significant. Our findings were different from several reports in the literature. Nassiri et al found no differences in mean IOP between the two groups at POD1, POW1, or POM1.[23] Rattan et al compared the incidence of IOP elevation at POM1 and found that, contrastingly, their standard group had a significantly higher rate of IOP elevation than the dropless group ($p = 0.04$).[7] Lindholm et al had no eyes on either group experience IOP elevation at any point in the follow-up period and there was no difference in mean IOP between patients with and without glaucoma in the dropless group. There is no

mention whether or not their glaucoma patients were kept on IOP-lowering drops postoperatively.[8]

One possible reason for the differences in our findings compared with that in the literature is the significant difference in the proportion of patients on IOP-lowering medications between the two groups. The higher number of IOP-lowering medications in the standard group at baseline compared with the dropless group is likely a result of selection bias. Shortly after the drop shortage, when most of the patients followed a dropless protocol, microinvasive glaucoma surgeries (MIGs) were introduced to our hospital. During this time, patients with IOP-lowering medications may have undergone combined cataract surgery with MIGs, resulting in exclusion from this study and, subsequently, leading to fewer patients who were on IOP-lowering medications in the dropless group. This not only can explain the higher percentage of patients on IOP-lowering medications in the standard group but may also explain the higher IOP in the dropless group. This is because patients often remained on their IOP-lowering medications postoperatively, potentially blunting IOP elevation after surgery. It should be mentioned that the selection bias in theory could have reduced the number of high-risk eyes in the dropless group that may have experienced IOP elevation, leading to an underestimation in the incidence of this event compared with the standard protocol, which could have resulted in significantly higher IOP in the standard group.

Posterior Capsular Opacification

The early PCO rate was significantly higher in the dropless group at 7 (3.1%) versus 2 (0.7%; $p = 0.042$). This may be a result from more inflammation in the AC at POW1 and POM1 in the dropless group as PCO development is triggered by inflammation.[24] Given the early occurrence, it is possible that what was described as PCO in the charts was residual lens material, which may also be related to more AC inflammation. We see no reason why the postoperative care should affect the amount of residual cortex, but it could affect cortical remnant clearance, which we chose to include in the definition of early PCO.

Limitations

This study carries the limitations of most retrospective studies. Data were collected from medical records by many different trainees in various stages of their education. Fortunately, the IOP and visual acuity outcome measures are generally considered standardized and easily compared between examiners.

The dropless technique was incorporated due to a shortage of topical drops, resulting in the case–control ratio not being 1:1 throughout each study period. Since both protocols were available simultaneously for part of the study, a selection bias for protocol choice was possible. Selection bias was minimized because drops were only used during shortages, if they were available. The more probable opportunity for selection bias was if attending surgeons alternatively chose dropless over drops, regardless of availability. The postoperative protocol was not selected by the residents, and the selection was made on the day of surgery, during which time it was known if prednisolone was or was not available. As mentioned earlier, selection bias may have resulted in more IOP-lowering medications in the standard group at baseline compared with the dropless group, due to the introduction of MIGs in the latter half of the study, as combined surgeries were excluded from the study.

An effort to control for different surgeons at different levels of training was achieved by having each arm of the study in a "March-to-March" period, so that the residents performing the surgeries were at the same point in training. An example of how the sequentially performed arms may have led to confounding is the significantly more miLOOP use in the dropless group. Follow-up was limited to 1 month, which precluded the possibility of more late complications, such as CME.

Prospective studies with longer follow-up times and more eyes should be performed to decrease previously mentioned retrospective limitations, identify slower developing complications, and compare rarer complications that require greater study power, such as endophthalmitis.

Conclusion

In this retrospective study of resident-performed cataract surgery, the dropless protocol was noninferior to drops in terms of visual outcomes and overall rate of postoperative complications. These findings agree with similar studies with experienced surgeons. However, it differs from studies of experienced surgeons in that there were significantly higher postoperative residual AC cells at POW1 and POM1 and more IOP spikes in the dropless group on POD1. We also found statistically significant higher rates of early PCO. In determining the risks and benefits of routine dropless resident-performed cataract surgery, the demonstrated overall safety of the dropless protocol, the inability to stop corticosteroids (if medically required), and the level of postoperative inflammation control needed should be considered.

Note

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Conflict of Interest

None declared.

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