



Office-Based Cataract Surgery

Population Health Outcomes Study of More than 21 000 Cases in the United States

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Purpose: To identify safety and effectiveness outcomes of office-based cataract surgery. Each year, approximately 3.7 million cataract surgeries in the United States are performed in Ambulatory Surgery Center (ASC) and Hospital Outpatient Department (HOPD) locations. Medicare in July 2015 published a solicitation for expert opinion on reimbursing office-based cataract surgery.

Design: Large-scale, retrospective, consecutive case series of cataract surgeries performed in Minor Procedure Rooms (MPRs) of a large US integrated healthcare center.

Participants: More than 13 500 patients undergoing elective office-based cataract surgery.

Methods: Phacoemulsification cataract surgery performed in MPRs of Kaiser Permanente Colorado from 2011 to 2014.

Main Outcome Measures: Postoperative visual acuity and intraoperative and postoperative adverse events (AEs).

Results: Office-based cataract surgery was completed in 21 501 eyes (13 507 patients, age 72.6±9.6 years). Phacoemulsification was performed in 99.9% of cases, and manual extracapsular extraction was performed in 0.1% of cases. Systemic comorbidities included hypertension (53.5%), diabetes (22.3%), and chronic obstructive pulmonary disease (9.4%). Postoperative mean best-corrected visual acuity measured 0.14±0.26 logarithm of the minimum angle of resolution units. Intraoperative ocular AEs included 119 (0.55%) cases of capsular tear and 73 (0.34%) cases of vitreous loss. Postoperative AEs included iritis (n = 330, 1.53%), corneal edema (n = 110, 0.53%), and retinal tear or detachment (n = 30, 0.14%). No endophthalmitis was reported. Second surgeries were performed in 0.70% of treated eyes within 6 months. There were no life- or vision-threatening intraoperative or perioperative AEs.

Conclusions: This is the largest US study to investigate the safety and effectiveness of office-based cataract surgery performed in MPRs. Office-based efficacy outcomes were consistently excellent, with a safety profile expected of minimally invasive cataract procedures performed in ASCs and HOPDs. *Ophthalmology* 2016;123:723-728 © 2016 by the American Academy of Ophthalmology.

Global estimates suggest that 94 million people are visually impaired because of cataract, and of these, 20 million are blind.¹ Because the incidence of cataracts increases with age, an increase in the elderly population will lead to a significant increase in cataract prevalence. Cataracts currently affect approximately 26 million Americans.² Approximately 25% of people in the United States aged 65 to 69 years have cataracts, a proportion increasing to more than 68% of those aged 80+ years.³

In 2014, approximately 23 million cataract surgeries were performed worldwide; of these, more than 3.6 million procedures were performed each in the United States and European Union.⁴ The estimated 2015 direct medical cost of cataracts in the United States approaches \$12 billion.¹ Cataract extraction with intraocular lens (IOL) implantation is the most commonly performed surgical procedure in the

United States. The main cost of cataract surgery is the facility fee, with Medicare reimbursement averaging \$964 for Ambulatory Surgery Centers (ASCs) and \$1670 for Hospital Outpatient Departments (HOPDs) in 2013.⁵ In addition to direct ophthalmic medical costs, cataracts incur significant direct nonophthalmic medical costs associated with vision loss (depression, injury, nursing home admission), direct nonmedical costs (caregivers), indirect medical costs of decreased employment and salary, and other societal costs.⁶

The safety and effectiveness outcomes of modern-day cataract surgery are well described in the literature.⁶ Until the 1980s, cataract surgery was primarily an inpatient procedure.⁷ Technologic advances have transformed cataract surgery so that now more than 99% are performed on an outpatient basis.⁸ More than 80% of cataract

surgeries in the United States today are performed in freestanding ASCs, with most of the remaining cases performed in HOPDs.⁹

Because cataract surgery has become minimally invasive and more procedural in nature, there has been increased interest in office-based cataract surgery,^{10,11} which may further streamline the surgical process by shortening scheduling delays until surgery, foregoing unnecessary preoperative workups and intraoperative anesthesia monitoring, and releasing valuable operating room capacity and resources.^{11–13} However, experience with office-based cataract surgery remains limited, with few studies on clinical outcomes and safety. Currently, Medicare and commercial third-party payers only pay a facility fee for cataract surgery undertaken in an ASC or HOPD, so physicians are disincentivized to perform the surgery in an office setting. However, the US Centers for Medicare/Medicaid Services has acknowledged the potential utility of office-based cataract surgery and has published a Request-for-Feedback memorandum regarding in-office cataract surgery.¹⁴

At Kaiser Permanente Colorado (KPCO) medical offices in the Denver, Colorado, metropolitan area, ophthalmologists have been performing cataract surgery in the minor procedure room (MPR) setting since 2006, typically with only 2 advanced cardiac life support–certified registered nurses (1 circulating and 1 monitoring/charting) and a surgical technician assisting. No anesthesiologist is present, and no intravenous lines or injections are routinely used. Only topical \pm intracameral anesthesia is generally used, with oral triazolam sedation.

Because office-based cataract surgery may provide significant advantages in patient convenience, procedural efficiency, and cost-savings, full characterization of its safety is indicated. The current investigation evaluated the safety and effectiveness of office-based cataract surgery, including the clinical outcomes of more than 21 000 consecutive cataract procedures performed in the MPR between 2011 and 2014.

Methods

Study Design and Records Search

This was a retrospective, consecutive case-series study of office-based cataract surgery performed in MPRs at 3 KPCO facilities. An institutional database search identified 21 501 cases of extracapsular cataract extraction/IOL implantation surgery (American Medical Association Current Procedural Terminology codes 66984/66982) that were performed from January 1, 2011, to December 30, 2014. All patients provided written informed consent to use their recorded data for anonymized research. The study protocol was approved by the KPCO Institutional Review Board, was Health Insurance Portability and Accountability Act compliant, and conformed to the Declaration of Helsinki.

Surgical Protocol and Follow-up

At KPCO, cataract surgery candidates are required to see their primary care provider within 1 year before surgery. Surgeons reviewed patient charts and performed a comprehensive

ophthalmological examination during the initial cataract evaluation and reviewed each patient chart again just before surgery, with focus on pertinent health problems. If intravenous sedation was used (infrequently for office surgery), then preoperative planning on the day of surgery included verifying nothing-by-mouth status, reviewing pertinent laboratory tests and imaging, if indicated, and performing a brief physical examination (heart, lungs, electrocardiogram, Mallampati score, and American Society of Anesthesiologists status). An emergency response “Nurse Stat” team with a crash cart was on standby duty at each of all 3 medical office buildings to manage any life-threatening intraoperative complications. Two of the 3 KPCO medical office buildings are physically linked to the parent hospital by enclosed walkways, and the third office complex is located approximately 1.5 km away from a KPCO-affiliated hospital.

For 1 day before surgery, patients self-administered topical polymyxin B sulfate/trimethoprim, prednisolone acetate, and diclofenac, 4 times per day. Patients arrived 1–1.5 hours before scheduled surgery, were positively identified, provided written consent, had blood pressure measured and chart reviewed, and received topical ocular mydriatic and anesthetic drops. The standard anesthesia regimen included oral triazolam anxiolysis/sedation at physician discretion, with topical tetracaine or lidocaine \pm intracameral lidocaine. The KPCO ophthalmologists rarely use retrobulbar anesthesia for office procedures. American Society of Anesthesiologist classification was reserved for the few patients who received general anesthesia. All patients underwent intraoperative electrocardiography, O₂ saturation, and blood pressure monitoring. Plethysmography was not used.

Phacoemulsification cataract extraction and IOL implantation were performed through a clear corneal incision. Postoperatively, patients were observed for approximately 10 to 15 minutes while discharge instructions were discussed, after which patients were delivered to the office building exit via wheelchair. Patients were prescribed a standard postoperative medication routine involving topical antibiotics (1 week), nonsteroidal anti-inflammatory drugs (4 weeks), and steroid (4 weeks). Standard patient follow-ups were performed 1 day and 1 month postoperatively, with all patient self-referrals for suspected ocular adverse events (AEs) documented and tracked during and beyond that point.

Outcome Measures

The primary outcomes analyzed in this study were best-corrected visual acuity and the incidence of intraoperative and postoperative AEs.

Results

Key comparisons between office-based and ASC or HOPD-based cataract surgery parameters are detailed in [Table 1](#). Office-based procedures do not involve dedicated anesthesiology personnel (e.g., MD or CRNA), preoperative laboratory evaluations are not customary, and intravenous access is not routinely established.

Of all surgical records screened at Kaiser Permanente for the study time period, 21 501 eyes of 13 507 patients met study eligibility criteria. Demographic and baseline ocular parameters are provided in [Table 2](#). Mean age at surgery was 73 years; 59% of patients were female. Numbers of left and right eyes were similar.

The most common systemic comorbidities were systemic arterial hypertension (54%), diabetes mellitus (22%), and chronic obstructive pulmonary disease (9%). The most common ocular comorbidities were nonexudative macular degeneration (12%), glaucoma (18%), and exudative macular degeneration (2%). Axial

Table 1. Cataract Surgery Parameters in Office-Based versus Ambulatory Surgery Center and Hospital Settings in the Kaiser Permanente Colorado Health Care System

Parameter	Office-Based	ASC/Hospital
Anesthesiologist or nurse anesthetist	No	Yes
Preoperative laboratory tests are routine	No	No
Preoperative medications used (prednisolone acetate, polymyxin B sulfate/trimethoprim, and diclofenac 4 times per day starting 1 day before surgery)	Yes	Yes
Ophthalmic anesthesia, type used or available	Topical Intracameral Subtenon Retrobulbar	Topical Intracameral Subtenon Retrobulbar
Surgical procedures performed	Phacoemulsification Manual ECCE IOL exchange Combined phacoemulsification/ trabeculectomy Combined phacoemulsification/PKP	Phacoemulsification Manual ECCE IOL exchange Combined phacoemulsification/ trabeculectomy Combined phacoemulsification/PKP
Intraoperative antibiotics (intracameral moxifloxacin or vancomycin)	Yes	Yes
Intraoperative IV access used	No	Yes
Intraoperative BP, O ₂ Sat, and EKG	Yes	Yes
Postoperative medications (prednisolone acetate, polymyxin B sulfate/trimethoprim, and diclofenac 4 times per day)	Yes	Yes
No. of technicians/RNs assisting	2 RNs/1 surgical technician	3

ASC = Ambulatory Surgery Center; BP = blood pressure; ECCE = extracapsular cataract extraction; EKG = electrocardiography; IOL = intraocular lens; IV = intravenous; O₂ Sat = arterial oxygen saturation; PKP = penetrating keratoplasty; RN = registered nurse.

length was >26 mm in approximately 4% of eyes. Antiangiogenic agents had been intravitreally administered within 60 days in 1% of eyes. Approximately 3% of eyes belonged to patients with a history of oral α -adrenergic antagonist (e.g., tamsulosin) use.

Of the 21 501 cases, 11.4%, 29.3%, and 59.3% were performed in 3 KPCO MPRs (Lone Tree, Franklin, and Rock Creek, CO, respectively) by 15 cataract surgeons. Phacoemulsification with IOL implantation was performed in 99.9% of eyes, whereas manual extracapsular cataract extraction was performed in 0.1% of eyes (Table 3). The IOL was placed inside the capsular bag in 99.0% of eyes. Implanted IOLs were from Alcon (86.8%), Advanced Medical Optics (12.2%), and Bausch & Lomb (0.9%); 2.9% of IOLs were multifocal.

The preoperative pupil dilating regimen achieved optimal dilation (>5 mm estimated pupillary diameter) in >95% of eyes. Perioperative patient sedation included oral triazolam in 76.3% of cases. Topical anesthesia included tetracaine eye drops in 99.8% of eyes, and topical and/or intracameral lidocaine was instilled in 51.2% of cases. Retrobulbar anesthesia was used in less than 0.03% of cases (6/21 501 eyes). Intracameral vancomycin was administered in all cases; intracameral moxifloxacin was also administered in 66.5% of cases, although our surgeon consensus has increasingly evolved during and beyond the study period to using vancomycin only.

Postoperative mean best corrected visual acuity was 0.14 ± 0.26 logarithm of the minimum angle of resolution units in operated eyes (equivalent of 20/28 Snellen; n = 21 428 eyes reported; 99.7% of cohort).

Intraoperative AEs included 119 cases (0.55%) of capsule rupture or tear and 73 cases (0.34%) of vitreous loss (Table 4). Iritis/uveitis was the most common postoperative AE, occurring in 330 eyes (1.53%). Retinal detachment within 90 days of operation occurred in 30 cases (0.14%), and cystoid macular edema was observed in 6 eyes (0.03%) during this period. No

cases of endophthalmitis within 30 days of surgery were reported. Ocular surgical reintervention was required within 6 months in 150 eyes (0.70%) (Table 5).

Of 21 501 cataract procedures, 3 patients received emergency department (ED) care on the day of surgery, although none required perioperative emergency intervention by our Nurse Stat teams while on-site. One hypertensive patient experienced severe headache after the cataract procedure and was driven to the ED by his wife for evaluation, and he was released. A second patient with a history of atrial fibrillation experienced near syncope in the evening after an 8AM cataract surgery was evaluated in the ED on cardiologist advice and was admitted for pacemaker implantation. A third patient had a fall several hours after discharge from cataract surgery and required hospitalization for blunt trauma chest injuries. These events are common in the elderly demographic of our cohort and were not definitively linked to the cataract procedure.

Discussion

Analysis of more than 21 000 consecutive office-based cataract surgeries demonstrates the safety and effectiveness of performing these procedures in the MPR. In the last few decades, stepwise technologic advances in phacoemulsification and foldable IOLs allowed cataract surgery to move to the ambulatory setting.⁸ In 1985, the United States required that Medicare-funded cataract surgery be performed, when practicable, on an outpatient basis and recalibrated their reimbursement schedule accordingly.¹⁵ This helped to launch the progressive relocation of cataract surgery from hospital-based inpatient wards to ASCs.^{8–11}

Table 2. Demographic and Baseline Clinical Parameters

Parameter	n (of 21 501 Eyes of 13 507 Patients)	% of Cohort
Age, yrs, mean \pm SD	72.6 \pm 9.6	
Sex, n, % of people		
Female	7946	58.8
Male	5561	41.2
Cataract details, n, % of eyes		
Congenital	48	0.2
Cortical	713	3.3
Nuclear sclerosis	4249	19.8
Polar	157	0.7
Traumatic	24	0.1
Unspecified/senile	16 310	75.9
Operated eye medical history, n, % of eyes		
Axial length >26 mm	925	4.3
Pseudoexfoliation syndrome	290	1.4
Previous vitrectomy	229	1.1
Macular degeneration (nonexudative)	2607	12.1
Macular degeneration (exudative)	440	2.1
Glaucoma	3927	18.3
Iritis	90	0.4
Topical eye medications,* n, % of eyes		
α -adrenergic agonist	251	1.2
β -adrenergic blocker	329	1.5
Prostaglandin	367	1.7
Carbonic anhydrase inhibitor	151	0.7
Cyclosporine	42	0.2
Pilocarpine	16	0.1
Intravitreal eye medications, [†] n, % of eyes		
Bevacizumab, aflibercept, or ranibizumab	211	1.0
Corticosteroid	3	<0.1
Antibiotic	0	0.0
Key systemic comorbidities, n, % of eyes		
Asthma	97	0.5
CHF	573	2.7
COPD	2020	9.4
Diabetes mellitus	4783	22.3
Systemic arterial hypertension	11 500	53.5

CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

Percentage values rounded to nearest single decimal place.

*Ocular topical drug use within 120 days before surgery.

[†]Injected antiangiogenics, steroid, and antibiotic within 60 days before surgery.

More recently, there has been an evolving trend to transition suitable outpatient surgeries from ASCs to individual physician offices.¹⁶ This shift has extended to ophthalmology, with the Medicare Program recently announcing that they “believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases.”¹⁴ At KPCO, cataract surgeries increasingly use the MPR as the default procedural setting. Referral to the ASC/HOPD setting is generally reserved for patients with extreme comorbidities that, in the physician’s opinion, increase their risk of complications or procedural discomfort. Also, cataract cases are occasionally moved from the office into the ASC/HOPD setting to fill allocated surgeon block time, and not

Table 3. Surgical Procedural Details and Observations

Surgical Parameter	N = 21 501 Eyes
Surgical technique, n (% of eyes)	
Phacoemulsification	21 484 (99.9%)
Manual extracapsular extraction	16 (0.1%)
Other	1 (<0.1%)
IOL placement, n (% of eyes)	
Capsular bag	21 275 (99.0%)
Anterior chamber	13 (0.1%)
Ciliary sulcus	73 (0.3%)
Not specified	140 (0.7%)
Intraoperative observations, n (% of eyes)	
Pupil diameter \leq 5 mm, estimated	1010 (4.7%)
Shallow anterior chamber	47 (0.2%)
Perioperative medications, n (% of eyes)	
Triazolam, oral	16 413 (76.3%)
Tetracaine, topical	21 452 (99.8%)
Lidocaine, topical or intracameral	11 013 (51.2%)
Lidocaine, retrobulbar	6 (<0.03%)
Vancomycin, intracameral	21 501 (100.0%)
Moxifloxacin, intracameral	14 294 (66.5%)
Visual acuity, postoperative, mean \pm SD	
logMAR, corrected, n = 16 158 (Snellen chart equivalent)	0.08 \pm 0.17 (20/24)
logMAR, uncorrected, n = 21 385 (Snellen chart equivalent)	0.32 \pm 0.31 (20/42)
logMAR, best of corrected or uncorrected, N = 21 428 (Snellen chart equivalent)	0.14 \pm 0.26 (20/28)

IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation.

Percentage values rounded to nearest single decimal place.

due to patient medical necessity. Nonetheless, at the onset of the study period (year 2011), 84% of KPCO cataract surgeries occurred in the office setting, increasing steadily to 93% of procedures performed in 2014; through the third quarter of 2015, >95% have occurred in MPRs.

Cataract surgery is now a safe outpatient procedure,⁷ and our experience with more than 21 000 cases extends these findings to the office-based setting. Our study population demographic was representative of the US population who typically undergo cataract surgery in terms of age,^{2,3,17} gender,^{3,17} and comorbidities.¹⁸ Overall vision outcomes were excellent, with mean postoperative best-corrected visual acuity of 20/28 Snellen. Surgical reintervention was required in only 0.6% and 0.7% of patients at 3 and 6 months postoperatively, respectively. Our reoperation rate was lower than the 90-day 2.11% postcataract surgery reoperation rate in a large cohort (N = 3310) at 2 US teaching hospitals.¹⁹ However, that 2014 report was limited to procedures performed by ophthalmology residents and included a significantly higher proportion of manual extracapsular extraction procedures (11.4% vs. 0.1% in the current study) that might be expected to have a higher complication rate.¹⁹

Uncommon yet serious and potentially vision-threatening AEs after cataract surgery include endophthalmitis, retinal

Table 4. Ocular Adverse Events from Office-Based Cataract Surgery

Ocular AE Parameter	N = 21 501 Eyes
Intraoperative AEs, n (% of eyes)	
Posterior capsule rupture	119 (0.55%)
Vitreous loss	73 (0.34%)
Postoperative AEs, n (% of eyes)	
Endophthalmitis within 30 days	0 (0.00%)
Hyphema within 30 days	5 (0.02%)
Retinal detachment/tear within 90 days	30 (0.14%)
Cystoid macular edema within 90 days	6 (0.03%)
Corneal edema between 1–3 mos	110 (0.51%)
Iritis/uveitis between 1–5 mos	330 (1.53%)
Surgical reintervention within 3 mos	131 (0.61%)
Surgical reintervention within 6 mos	150 (0.70%)

AE = adverse event.

detachment, and choroidal/suprachoroidal hemorrhage.⁷ A 2013 meta-analysis of 42 studies comprising more than 6.6 million cataract surgeries recognized a large variation in the rate of postoperative endophthalmitis, ranging from 0.012% to 1.3% in reports since 2000.²⁰ The analysis also acknowledged a clear decade-by-decade decrease in endophthalmitis rates since the 1970s. We encountered no cases of postoperative endophthalmitis in our large cohort. This is likely a reflection of the experience gained by our surgeons in performing office-based cataract procedures in a high-volume setting, coupled with our routine administration of intracameral antibiotic prophylaxis.^{20–22}

Retinal detachment is a vision-threatening AE that may occur after cataract surgery.⁷ Our patients experienced a 0.14% retinal detachment incidence during the 3 months after surgery. This rate is consistent with previous reports of 0.26% and 0.27% retinal detachment recorded 12 months postoperatively in similar patient populations.^{23,24}

Iritis/uveitis occurring 1 to 5 months postoperatively was the most frequent AE, affecting approximately 1.5% of operated eyes. Other AEs such as macular edema and hyphema occurred with low incidence. All of these AEs resolved.

Table 5. Reasons for Secondary Surgery within 6 Months after Office-Based Cataract Surgery

Surgical Procedure	No. of Eyes*
Corneal repair of surgically induced astigmatism	1
Corneal incision suturing	9
IOL exchange	44
IOL insertion, not concurrent with lens removal	22
IOL repositioning	17
Iris/ciliary body repair/suturing	3
Lens fragment removal	29
Retinal detachment repair, all methods	11
Vitreous strand severing, laser	3
Vitrectomy, all methods	16

IOL = intraocular lens.

*A total of 155 procedures that were possibly or probably related to the cataract procedure were performed in 150/21 501 (0.70%) of study eyes.

Intraoperative posterior capsular rupture and vitreous loss occurred in approximately 0.6% and 0.3%, respectively, of study eyes. This incidence was lower than the 3.5% rate previously reported in a study of >45 000 cataract extractions.²⁵ Posterior capsule tears are associated with retinal detachment,²⁶ reportedly accounting for 37% of detachment risk in patients undergoing cataract surgery.²⁷ However, our patients had low rates of both posterior capsule rupture and retinal detachment.

Extensive preoperative laboratory evaluations are routinely prescribed to patients undergoing cataract surgery in ASCs and HOPDs, although such testing neither reduces AE incidence nor improves patient outcomes.^{12,28} Nevertheless, preoperative testing remains as prevalent as it was 20 years ago, at great expense, although practice guidelines clearly emphasize that this testing is unnecessary.¹² By contrast, office-based cataract procedures such as those performed in this study do not routinely require preoperative laboratory tests, significantly reducing direct medical costs.

Another key difference between office-based and ASC- or HOPD-based cataract surgery is that office-based procedures at KPCO do not require intravenous access, and an anesthesiologist or nurse anesthetist is not present or on staff. Anesthesia care provided by registered nurses in office settings is comparable to the care provided in ASCs and hospitals, especially when offices are accredited and their personnel are board-certified.²⁹ A 2015 report detailed phacoemulsification performed on 6961 eyes of 4347 patients, assisted by 2 registered nurses and without the dedicated presence of or access to anesthesia services.¹¹ In that study, only 3 perioperative AEs (0.04% of cases) occurred that required emergency intervention; all were vasovagal collapse that resolved uneventfully without hospital admission. Thus, office-based anesthesia and cataract surgery can be performed safely in appropriate office settings.

Cataract surgery performed in the MPR provides safe and effective outcomes while streamlining patient care.^{11,14} Our experience with more than 21 000 cases performed in the MPR demonstrated satisfactory postoperative visual acuity and a safety profile well within expectations for modern cataract surgery.

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Abbreviations and Acronyms:

AE = adverse event; **ED** = emergency department; **KPCO** = Kaiser Permanente Colorado; **HOPD** = Hospital Outpatient Department; **IOL** = intraocular lens; **MPR** = Minor Procedure Room.

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