



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

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