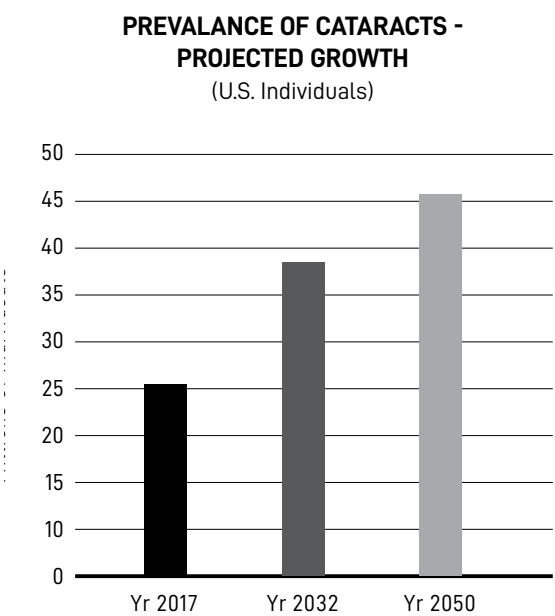


As Demand for Cataract Surgery Continues to Increase, Office-Based Surgical Suites Can Offer a Better Solution for Surgeons and Patients.

More than fifty years ago, ophthalmic surgeries were performed exclusively in hospitals. Patients experienced extended hospital stays, recovery times that lasted for weeks, greater post-operative risks, and costs that were 251 times higher than those of today. Then, in 1970, the first Ambulatory Surgery Center (ASC) opened in the U.S., ushering in an alternative to hospital-based ophthalmic surgery that provided a high quality, more cost-effective option to inpatient and outpatient hospital care. Fifteen years later, the 1986 ruling that allowed certain Medicare-covered procedures to be performed in hospital outpatient departments (HOPD) and ASCs escalated the move away from hospitals for cataract surgery.

Compared to hospitals, ASCs proved to be safe and efficient locations for surgery that also reduced scheduling delays. In addition, ASCs offered surgeons more complete control of the process with respect to items that affect surgery. With ASCs, obstacles to updating or acquiring new equipment, implants and supplies typically encountered because of hospital budgets and policy changes were not a factor. And because ASC decision making was more focused and specialized, it allowed for better patient care.

Today, the demand for ophthalmic surgery continues to grow with the aging Baby Boomer population. Per Prevent Blindness', "Future of Vision: Forecasting the Prevalence and Cost of Vision Problems," in 2017 the U.S. population of those age 65 and older was 51 million, over half of whom – 25.7 million – had cataracts. Cataract surgery was the most common outpatient surgery, with 3.8 million¹ surgeries performed, an incidence rate of 7.5%. By 2032 it is projected that the number of individuals in the U.S. with cataracts will increase to 38.5 million and by 2050 that number will reach 45.6 million.



Not only is the demand for cataract surgery projected to increase with the aging population, the demand for presbyopic refractive procedures is also increasing with the projected market cap growth in excess of 1000% in the next ten years. Along with the forecast growth in these procedures, it is anticipated that there will be an even greater shortage of operating rooms than currently experienced and a shortage of physicians to keep up with demand. While there are currently more than 5,400 ASCs, with more than 1,000 specializing in ophthalmic surgeries,² that number is insufficient to keep up with the projected demand. In addition, more and more profitable outpatient hospital cases are being brought to ASCs such as total joints, spine procedures, pacemakers, and cardiac stents, further reducing available operating room time. Clearly, another solution is needed.

Just as a shift took place from hospital-based surgery to ASCs, a shift to Office-Based Surgery (OBS) can address the shortage of operating rooms, and become the future standard for ophthalmic surgical procedures for relatively low risk patients. OBS suites operate at the

same safety standards as ASCs and hospitals, are regulated in all 50 states, and operate under the physician's license governed by the individual State Board of Medicine using either Class A (oral sedation, e.g., valium) or Class B (monitored) anesthesia.

	Class A	Class B
Type of Sedation	<ul style="list-style-type: none">• Oral sedation, e.g., valium	<ul style="list-style-type: none">• Monitored anesthesia
Office Spaces Needs	<ul style="list-style-type: none">• Most LASIK are eligible to serve as an office-based surgery suite with no additional construction• As little as 700 SF from existing procedure rooms can be converted to an office-based surgery suite	<ul style="list-style-type: none">• Dedicated areas needed• Operating room, including pre-op and post-op areas, separated from general office
Post-Op Requirements	<ul style="list-style-type: none">• None	<ul style="list-style-type: none">• Supervision of RN, CRNA or Anesthesiologist• Patient monitoring equipment
Insurance Reimbursement	<ul style="list-style-type: none">• Commercial Insurance• Medicare Advantage	<ul style="list-style-type: none">• Commercial Insurance• Medicare Advantage

Safe and Effective, OBS is Advantageous for Patients and Physicians.

Compared to ASCs, the advantages of OBS suites are many, for both patients and physicians. Because the surgery takes place in the physician's office, patients are interacting with staff they know, and they are in an environment with which they are familiar, thus increasing their comfort and reducing their anxiety. OBS suites are also a more convenient option for patients as the exam and surgery can be performed on the same day, eliminating the need for redundant pre-op work and an overall shorter surgical process. Surgeries performed in an OBS suite are also most cost effective, something that will be increasingly important with the growth of healthcare consumerism, as patients seek greater transparency in costs and play a more active role in choosing where to have their surgery performed.

Of primary importance, office-based surgery provides safe and effective outcomes that are comparable or superior to those performed in an ASC while also streamlining patient care. The largest U.S. retrospective study of 21,501 cataract surgeries (13,507 patients, age 72.6 ± 9.6 years) conducted in the Denver metropolitan area Kaiser office from 2011-2014 found that OBS efficacy outcomes were consistently excellent, with a safety profile expected of minimally invasive cataract procedures performed in ASCs and HOPDs. 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%). Good visual outcomes and safety were reported with 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, and postoperative complications were low.³

In addition to excellent safety and efficacy, procedures performed in an office-based setting have the advantage of utilizing the practices' own surgical staff that provides a specialized level of skill and care, focused on ophthalmic office-based procedures. The OBS staff also takes ownership of outcomes as they are with the patient at every step – from exam to preop to intraop to postop. This is in contrast to ASC staff whose skill is for varied surgical procedures and with ownership only of the surgery itself.

OBS Suites Reduce Costs.

Office-based surgeries also reduce the cost of care. Unlike surgeries performed in ASCs and HOPDs which routinely prescribe extensive preoperative laboratory evaluations that do not reduce AE incidence nor improve patient outcomes, office-based cataract procedures such as those reported in the Kaiser study do not routinely require preoperative laboratory tests, significantly reducing direct medical costs. In addition, more than 95% of patients that qualify for OBS procedures do not use or require monitored anesthesia care, thus eliminating the \$125-\$850 per case cost. This can result in an annual savings of \$552 million and a reduction of Centers for Medicare & Medicaid Services (CMS) oversight. Moreover, because OBS surgeries require less licensed personnel, staff costs can be reduced by 25%.^{3,4}

Physicians garner advantages with an Office-Based Surgery suite. By integrating clinic and surgery in one location they have more control and ease of scheduling, giving them the flexibility to see more patients per day. Physicians are also able to provide better continuity of care for their patients and have a better experience themselves given that the exam, preop, intraop, and postop all take place within their own offices.

Of importance, performing surgery in an OBS suite provides physicians with accurate and complete patient outcome data. Currently there is no monetary incentive for ASCs to provide records to the physician. As such, data is not shared by the ASC which holds some preoperative data and all intraoperative records but no postoperative

data. An example of why complete records is so important would be a case of an endophthalmitis infection. Should this occur, the physician would need to understand the cause and source of the infection – e.g., during preop surgical tool prep, during surgery or post surgery – to accurately correct and prevent repeat occurrences. When performing surgery in an Office-Based Surgery suite, physicians have all three aspects of the patient's surgical data in one place, leading to improved outcomes.

From a financial standpoint, there is potential to increase practice revenue with an OBS suite. By integrating clinic and surgery in one office location, physicians may increase patient capacity and retain surgical revenue within their practice. Furthermore, third-party payers (insurance companies), Medicare and Medicare Advantage often provide additional reimbursements for procedures performed in an Office-Based Surgery suite, at a similar rate as an ASC, depending on the specialty and type of cases being performed. Of note, while CMS does not currently reimburse facility fees for OBS cataract surgery, the issue is under review following a 2016 request for information in the Medicare Physician Fee Schedule Proposed Rule. CMS stated, "Advancements in technology have significantly reduced operating time and improved both the safety of the procedure and patient outcomes." It was further stated that "We believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. For example, routine cases in patients with no comorbidities could be performed in the non-facility surgical suite, while more complicated cases (for example, pseudoexfoliation) could be scheduled in the ASC or (hospital outpatient department)."⁵

Obstacles to Building OBS Suites.

While there are numerous advantages, some physicians do not consider Office-Based Surgery for their practice because of a lack of knowledge. This includes uncertainty about how to go about space planning and the time and costs required for the OR build-out. Some physicians assume they don't have the space necessary to create an OBS suite – though most existing LASIK suites are eligible to serve as an OBS suite with no additional construction, and as little as 700 SF from existing procedure rooms can be converted for office-based surgery.

Insurance acquisition for an OBS suite can also be intimidating as is lack of expertise in accreditation and compliance, given variations in local, state and national standards. Additionally, many physicians are unaware or unsure of OR equipment needs, and have concerns about surgical staff training.

While all of these are perceived barriers for many physicians, the fact is that more than 100 ophthalmology Office-Based Surgery suites have already been successfully established in the U.S. over the past decade. Lance Kugler, M.D, with a practice in Omaha, Nebraska, worked with a company specializing in creating OBS suites to upgrade his existing LASIK center for Office-Based Surgery. Remarking on the ease of establishing his OBS suite, he noted that the process was seamless and that "They were able to guide us through the development and implementation of the OBS suite from start to finish." He further observed that "By moving to an office-based setting, the ability to control costs is much greater and therefore margins are higher compared to ASCs which have many levels of overhead that add unnecessary expense to the process." He also noted that patients have a more favorable experience, stating "Surgeons are used to taking patients to a third-party ASC and consider it routine, but for patients it's a big deal to go to another entity that is new to them. Moving procedures into our own facility has removed that barrier and led to more patients choosing to have their procedures with us."

1. Data Research - <https://idataresearch.com/over-3-8-million-cataract-surgeries-performed-every-year/>.

2. An open letter from the president of OQSS. Outpatient Ophthalmic Surgery Society. https://ooss.org/wp-content/uploads/OQSS_SEE_-MFS_Rule_Comments_Office-Surgery_.pdf. Accessed Feb.11, 2019.

3. Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Office-Based Cataract Surgery: Population Health Outcomes Study of More than 21 000 Cases in the United States. *Ophthalmology*. 2016 Apr;123(4): 723-8.

4. Gangadhar B. Cataract Surgery: The Road to Fiscal Sustainability The Promise of the Triple Aim. Presentation at Kansas EyeCon 2019. April 26, 2019; Leawood, KS.

5. Hasson M. CMS Assesses Office-based Cataract Surgery, *Ocular Surgery News U.S. Edition*, April 10, 2016.