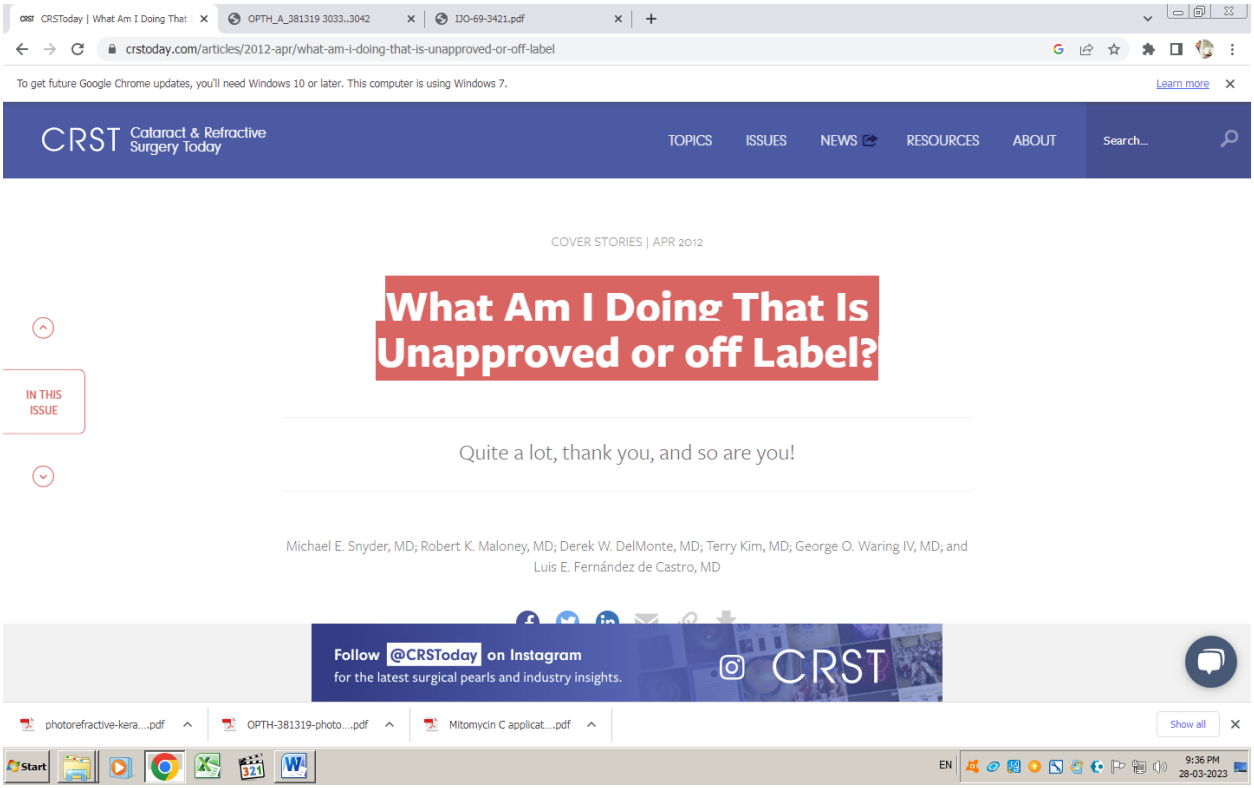
What Am I Doing That Is Unapproved or off Label?



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What Am I Doing That Is Unapproved or off Label?

Quite a lot, thank you, and so are you!

Michael E. Snyder, MD; Robert K. Maloney, MD; Derek W. DelMonte, MD; Terry Kim, MD; George O. Waring IV, MD; and Luis E. Fernández de Castro, MD

Quite a lot, thank you, and so are you!

By Michael E. Snyder, MD

A lot of what I do for my patients is off label or not approved by the FDA. That is true for all of us ophthalmologists, although some of us might not be aware of it.

A BRIEF PRIMER

The term *off label* means that we are implanting, prescribing, or otherwise using a medical product for an indication different from that approved by the FDA. When a company submits a new product to the FDA, approval is based on the studies that have been performed and submitted to the agency, and the label states the indication for which the approval was granted. Many times, the primary market to which a product is sold has little, if anything, to do with its labeling or the studies for which it was approved.

For example, no topical antibiotic is currently approved for endophthalmitis prophylaxis. Prescribing the drugs for this purpose, as I do, is off label but not illegal. Actually, it is the standard of care. Similarly, nearly all antibiotic treatments for corneal ulcers are off-label uses; only ciprofloxacin and ofloxacin are approved for this indication.

As a second example, interferon a-2b is approved for renal carcinoma but not conjunctival intraepithelial neoplasia. Topical interferon is an incredibly useful and versatile tool for the treatment of ocular surface squamous tumors with, as of yet, no documented side effects. It has a high safety profile, but its ophthalmic use is off label.

The off-label paradigm is not restricted to the prescription pad. Until the approval of trypan blue (VisionBlue; DORC International BV), we used indocyanine green (IC Green; Akorn, Inc.) to stain the anterior capsule in cases of white cataract. Most of us have now abandoned this complex dilution, although I still select indocyanine green for congenital aniridics. Their anterior capsules are thinner and more friable and can be negatively affected by trypan blue, which reduces capsular elasticity. I also find trypan blue indispensable for the capsulorhexis in pediatric eyes, since the dye (in this case favorably) reduces the elasticity of the stretchy anterior capsule (Figure 1). This indication is an untested (as far as the FDA) and off-label use of trypan blue.

Most, if not all, commonly used IOLs are not approved for use in children, yet we would be loathe to leave all children aphakic. I tediously counted every IOL currently approved for use with suture fixation. The final sum is … zero. Moreover, no sutures are labeled for scleral or iris fixation. In fact, my favorite for this use, polytetrafluoroethylene (Gore-Tex; W. L. Gore & Associates, Inc.) is not even labeled for ophthalmic use. Similarly, the antimetabolites 5-fluorouracil and mitomycin C (MMC) are commonly used off label in glaucoma surgery. Some surgeons also regularly use MMC off label to reduce haze after PRK or as an adjunctive therapy to pterygium excision. In addition, ocular oncologists perform intravitreal injections of MMC for intraocular lymphoma, among other esoteric vitreoretinal applications, none of which carries formal FDA labeling.

The aforementioned examples are just those that came quickly to my mind.

SPECIAL CIRCUMSTANCES

Exemptions

When the FDA has not approved a product, it may not be imported, sold, or implanted except under special circumstances, which fall into two categories. The first consists of products implanted under formal FDA investigational device exemption or humanitarian device exemption studies, and the second comprises implantations under a compassionate use device exemption (CUDE). The latter requires an independent request to the FDA for permission to use a product or device on a case-by-case basis. If the exemption is granted for that particular case, careful monitoring of its use by both the clinician-investigator and an independent institutional review board is required, with follow-up information provided to the FDA. The granting of a CUDE is not an FDA imprimatur of safety. Rather, we are required to notify the patient in writing (and gain informed consent for the product's use in this setting) that the FDA has not tested the device for safety and that its use is investigational. Typically, the FDA will consider a CUDE when no other reasonable alternative is available.

In our practice, my colleagues and I have used the CUDE process for artificial iris cases and peculiar IOL needs. I will share two representative cases.

Example No. 1

Several years ago, a young schoolteacher presented with leukocoria in a blind eye from chronic retinal detachment.[1] She thought that her potential suitors would constantly stare at her white pupil and said that her students were frequently distracted by it, inhibiting her effectiveness in the classroom. Under a CUDE, the surgeon secured a specially made black PMMA implant in the

ciliary sulcus, eliminating the leukocoria and profoundly improving the patient's selfimage and self-confidence. In this case, no product existed to solve her problem, so the unique solution required was obviously not met by FDA-approved devices.

Example No. 2

A newborn baby with axial congenital cataract had been treated with multiple sphincterotomies, which not only failed to reduce her amblyopia but also left her severely photophobic (Figure 2). Although the cataract was subsequently removed, amblyopia therapy failed to progress and, further, was hindered by habitual forced lid occlusion resulting from persistent photophobia. After the failure of conservative management, at age 3, she was referred to our practice for iris repair. The surgeon performed a cerclage (purse-string suture) repair of the iris, which resolved the patient's glare symptoms and allowed some progress with amblyopia treatment. Sadly, after 2 years, the cerclage suture cheese-wired, and the photophobia returned. The surgeon performed a second suture repair with numerous imbricating sutures. The procedure relieved the patient's photophobia but again lasted only 18 months, after which intolerable symptoms returned, resulting in both photic discomfort and a facial spasm from secondary lid closure.

Because no reasonable alternative was available, the surgeon was able to obtain a CUDE for a customized artificial iris. The implantation of a CustomFlex (HumanOptics AG) resolved the patient's glare and light sensitivity, and her smile returned.

CONCLUSION

The FDA serves an important role by protecting patients. The agency's formal approval of devices has become increasingly costly, however, and the regulatory process uncertain. Accordingly, industry only seeks the FDA's approval of

devices and indications when the perceived marketplace is large enough to offset these barriers. In many instances, the proper, ethical care of patients requires the off-label use of products and, sometimes, even the use of medications and devices not approved by the FDA. It is incumbent upon us to provide effective options to our patients and to be familiar with the regulatory environments within which these options may exist. In light of the rising cost of regulatory approval, we can expect more of our care for patients with "unprofitable" diseases or conditions to fall into these categories.

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The most effective things I do fall into these categories.

By Robert K. Maloney, MD

The most effective things I do are unapproved or off label.

CATARACT SURGERY

I perform cataract surgery, a procedure that has never been approved by the FDA. Although the agency approved IOLs for use in cataract surgery, none is approved for use in IOL exchange, an important rescue procedure. At the conclusion of cataract surgery, I inject topical moxifloxacin, an off-label use, based on evidence that injecting a similar antibiotic (cefuroxime) reduces the risk of endophthalmitis.[1] The only approved use for topical moxifloxacin is the treatment of bacterial conjunctivitis, an indication of minimal benefit because

the disease is self-limited. On the other hand, I find topical moxifloxacin very useful for the unapproved treatment of bacterial keratitis.

REFRACTIVE SURGERY

I regularly perform LASIK to correct refractive errors after the implantation of premium IOLs, although the procedure is not approved for patients who have undergone cataract surgery. I always use a nomogram adjustment to improve the accuracy of LASIK, but nomogram adjustments are not FDA approved. Even routine LASIK patients are, therefore, undergoing an off-label procedure in my practice. In the relatively uncommon instance when one of my patients requires a LASIK enhancement, I do not hesitate to proceed, even though retreatments are unapproved.

Preoperatively, I measure patients' manifest refraction— an unapproved procedure. Nor is the phoropter an approved device. I also examine patients' eyes at the slit lamp, another unapproved device. I assess the fundus with an indirect ophthalmoscope, the safety and effectiveness of which have never been demonstrated to the FDA's satisfaction.

COMMUNICATION

Many medical procedures are not approved by the FDA, including appendectomy, coronary artery bypass graft, excision of a lung tumor, removal of an intracranial meningioma, and splinting of a broken limb. Unfortunately, it is more difficult than it should be to obtain information about highly effective, unapproved procedures, because companies are not allowed to communicate this information to physicians. Companies that do risk hefty fines. Communication between physicians is now regulated by the continuing medical education authorities, so a free exchange of ideas is no longer possible at most meetings.

This brings me to the unapproved procedure that I perform most often: talking to patients. Of course, discussions with patients of all their options have not yet been proven safe and effective. How long will it be before I am forbidden to talk about unapproved treatments like an IOL exchange or splinting a fracture?

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We are using cyanoacrylate glue in ophthalmology.

By Derek W. DelMonte, MD, and Terry Kim, MD

Cyanoacrylate and related compounds are fast-acting adhesives that have been used for everything from model airplane construction to dental repair. Initially discovered by researchers trying to find a suitable, clear, gun sight plastic in the 1940s, cyanoacrylate's utility as a “super glue” became evident, and it was made commercially by the Kodak company under the name Eastman 910 soon thereafter.[1] Although cyanoacrylate glues were reportedly used in the Vietnam War to retard bleeding in wounded soldiers, they were not officially approved by the FDA for human use until 1998 with the release of Dermabond (Ethicon, Inc.).[2] Despite the adhesives' success for the treatment of many ailments involving just about every part of the human body, their use remains off label in ophthalmology. Nevertheless, surgeons use cyanoacrylate glue as an office-based artificial corneal patch graft for patients with corneal melts (Figure 1), perforations, or wound leaks; to close the skin in oculoplastic procedures; as a temporary tarsorrhaphy in exposure keratopathy; and to facilitate occlusive therapy for amblyopia.

WHY GLUE?

Cyanoacrylate glue may be useful for eyes with corneal disorders in the acute setting. For example, quickly patching an area of bare corneal stroma prior to reepithelialization may prevent the production of additional collagenase at the site of melting corneal stroma.[3] In cases of infectious perforation, delaying the need for a penetrating keratoplasty can allow significantly more time for anti-infectious therapies to be effective, thereby increasing the chance of success of a future corneal graft (Figure 2). Because cyanoacrylate glues also have an intrinsic bacteriostatic activity against gram-positive organisms, they help create a barrier against the intraocular extension of some infections.[4]

In some instances of an acute penetrating injury, sealing the perforation with glue can eliminate the need for future surgical intervention. Particularly with small, clean penetrating injuries, the corneal stroma can heal under the hardened glue and eventually shed the patch, leaving an intact, healed cornea in its place. Moreover, in patients with a corneal perforation who are difficult to bring to the OR for other medical reasons, closing the eye with cyanoacrylate glue will help prevent endophthalmitis, significantly improving the eye's long-term prognosis.

Despite their value in corneal patching, cyanoacrylate glues are not acceptable for scleral applications. A severe inflammatory reaction incited by the glue was found to inhibit collagen remodeling in several studies.[5]

APPLICATION

Cyanoacrylate glues can be successfully applied in many different ways. The direct application of these adhesives to the bed of a thinning ulcer, with or without an overlying amniotic membrane or biologic patch graft, effectively prevents progressive thinning. This technique is useful in patients with various ulcerative disorders, including autoimmune stromal melts, chemical burns, neurotrophic ulcers, and radiation keratitis.[6] Some surgeons also place a

bandage contact lens over the treated area in an attempt to seal the lens to the ocular surface and increase protection of the area as it heals. Keeping a contact lens in place long term, however, increases the risk of infection.

In our practice, we have found that less is more when using cyanoacrylate glue for corneal pathology. By directly applying a very thin layer of glue to the base of an ulcer, we can safely seal the area while avoiding a large, irregularly elevated “glue foreign body,” which can be uncomfortable for the patient and can damage the surrounding anatomy. An overlying bandage contact lens can increase the patient's comfort and prevent movement of the eyelids from dislodging the glue prematurely. When we use bandage contact lenses, we try to avoid its adhesion with glue so that we may change the lens as necessary to help avoid the infectious complications of long-term wear. Given the favorable safety profile of this therapy, we generally attempt to glue all melting ulcers and perforations prior to surgical planning. We find that this measure allows us additional time for determining future intervention, thereby increasing our chances of successful longterm outcomes.

ADVANTAGES OF CYANOACRYLATE OVER OTHER ADHESIVES

Although other adhesives have been developed since the first use of cyanoacrylate, most notably biologic adhesives such as two-part fibrin-based glue, cyanoacrylate retains many advantages. It does not require a complex preparatory process and can be used quickly in an office setting. It is far less expensive than newer biologic adhesives. Finally, cyanoacrylate adhesives do not require refrigeration or other special conditions for storage, which makes them ideal for emergency departments or office-based practices. These advantages make cyanoacrylate an effective and efficient office-based treatment modality for perforated or thinning corneas.

Nonetheless, cyanoacrylate glue carries several limitations, including a brittle, hard consistency, an opaque nature, and an ability to incite corneal inflammation and neovascularization. We hope that adhesives or sealants under development specifically for ophthalmic use will represent significant improvements over both cyanoacrylate glue and current biologic adhesives.

CONCLUSION

Cyanoacrylate glues have become an important part of our corneal practice and will continue to be for the foreseeable future. With proper use, cyanoacrylate glues can be a safe and effective alternative to emergency surgery, and they can greatly improve the long-term prognosis of many eyes.

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Terry Kim, MD, is a professor of ophthalmology at the Duke University School of Medicine, and he is the director of ophthalmology fellowship programs and associate director of the Cornea and Refractive Surgery Services at Duke University Eye Center in Durham, North Carolina. He acknowledged no financial interest in the product or company mentioned herein. Dr. Kim may be reached at (919) 681-3568.

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We administer intracameral steroids and antibiotics at the conclusion of cataract surgery.

By George O. Waring IV, MD, and Luis E. Fernández de Castro, MD

At approximately 3 million procedures annually, cataract surgery is one of the most commonly performed surgeries in the United States.[1] The success of many medical treatments relies on the correct use of drugs with respect to dosage, frequency, continuity, and compliance. Between 30% and 60% of patients with illnesses do not adhere to prescribed medical therapy, however, which can lead to adverse effects and disease progression.[2] Improving surgical outcomes and minimizing recovery time are the keys to satisfied patients and a successful medical practice. Intracameral prophylactic medications are one method for making cataract surgery simpler and potentially safer.

ANTIBIOTICS

Infectious postoperative endophthalmitis is a rare but catastrophic complication of intraocular surgery. Its incidence after cataract surgery is approximately 0.07%.[3] Although ophthalmologists' use of intracameral antibiotic prophylaxis for the prevention of endophthalmitis in cataract surgery is controversial, the practice is supported by a growing body of evidence. The results of the European Society of Cataract and Refractive Surgeons' endophthalmitis study suggested that patients who received intracameral cefuroxime had a lower incidence of endophthalmitis than those who did not or who received topical antibiotics.[4,5]

The ideal intracameral antibiotic agent would be broad spectrum, bactericidal, fast acting, and nontoxic. Fourth-generation fluoroquinolones have been used in pre- and postoperative topical antibiotic regimens for cataract surgery because

of their broad spectrum of action as well as their overall safety and tolerance by vital intraocular tissues. Commonly used intracameral antibiotics include vancomycin, moxifloxacin, and cefuroxime. Moxifloxacin 0.5% ophthalmic solution has a broad spectrum of antimicrobial action, is readily available, and is preservative free. For these reasons, we routinely perform an intracameral injection of preservative-free moxifloxacin after routine and complex cataract surgery. Because aqueous turnover is swift, we supplement the drug's use with the topical administration of a commercially available preparation of topical moxifloxacin.

STEROIDS

Ophthalmologists have used steroids topically and subconjunctivally to treat inflammation after cataract surgery. Although effective for this purpose, the topical agents have several disadvantages, including the requirement of the patient's compliance with prescribed dosing, cost, and exposure of the ocular surface to preservatives. Despite a report that the concentration of intravitreally injected triamcinolone acetonide in aqueous humor is nontoxic,[6] surgeons still have concerns about the intracameral use of steroids. It is not uncommon for residual triamcinolone to resemble anterior chamber cell and/ or hypopyon during the early postoperative period. The drug can be distinguished from toxic anterior segment syndrome or infectious endophthalmitis, however, by the absence of fibrin, injection, pain, corneal edema, and other signs and symptoms associated with more sinister conditions.

We do not routinely use intracameral triamcinolone in patients with high-risk glaucoma or known steroid responders due to the risk of a steroid response. We do, however, feel its use is important for quelling postoperative inflammation in cases of combined phacoemulsification and endocyclophotocoagulation. We

supplement this therapy with topical steroids as needed and treat postoperative elevations in IOP in the usual fashion.

Although further studies are needed, theoretically, the intracameral injection of triamcinolone may decrease the incidence of postoperative cystoid macular edema. In the event of vitreous presentation, the drug improves the strands' visibility for assessment and subsequent management. Additional benefits of preservative-free intracameral triamcinolone acetonide are that it renders patients' compliance a nonissue, it is cost-effective, and it generally produces quiet eyes with minimal postoperative inflammation.

A preservative-free, pre-prepared mixture of intracameral moxifloxacin and triamcinolone acetonide can be ordered from a compounding pharmacy. We routinely inject this solution at the end of the case, with the cannula's tip placed under the iris to encourage posterior penetration. It is important to advise patients and their families that the milky suspension can temporarily blur vision on the postoperative day but that this side effect will gradually resolve.

CONCLUSION

Intracameral prophylactic therapy at the conclusion of cataract surgery appears to be a low-risk procedure. Injections spare patients the cost of a postoperative medication and reduce the number of drops they must remember to instill. Further studies are needed, however, to evaluate the safety and efficacy of intracameral prophylactic therapy for routine and complex cataract surgery.

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COVER STORIES | APR 2012

Same-day Bilateral Refractive Lens Exchange

If demonstrated to be safe, this procedure may become a desirable option for patients who elect to pay privately for vision correction.

Daniel S. Durrie, MD

Refractive surgeons are experiencing an exciting paradigm shift in lens surgery that is best characterized as a move from traditional lens surgery to the premium channel. In the traditional model, a third party pays; when premium services are rendered, however, patients are financially responsible. Traditionally, we surgeons aimed to optimize patients' BCVA after standard cataract surgery. Today, we strive to optimize their UCVA at both near and distance for a lifetime. The traditional model is characterized by phacoemulsification and the implantation of a monofocal IOL at an ambulatory surgery center. With the advent of the premium IOLs, refractive cataract surgeons are using femtosecond lasers and implanting toric and presbyopiacorrecting IOLs. In the future, we may even perform lens surgery in an in-office refractive suite. Compared with the traditional emphasis on cases per hour and controlling costs, the premium model focuses on exceeding patients' expectations.

INTERNATIONAL POPULARITY

The shift to the premium channel presents an opportunity for us to consider bilateral same-day lens surgery. Steve A. Arshinoff, MD, FRCSC, has been gathering data for many years on techniques for and the safety of bilateral, simultaneous cataract surgery—more accurately referred to as *immediate, sequential, bilateral cataract surgery* (ISBCS). This procedure is being performed with increasing frequency worldwide, owing to its medical merits and cost savings realized by health care systems offering ISBCS.[1] In Finland, many hospitals have a rate of ISBCS approaching 50% of cases, and in the Canary Islands of Spain, 80% of cataract procedures are performed as ISBCS (data on file with the International Society of Bilateral Cataract Surgeons). Ten percent of ESCRS members report routinely performing ISBCS.[2] Considerable published evidence shows ISBCS to be at least as effective as delayed, sequential, bilateral cataract surgery, and no published articles show that the former is less safe.[3]

BILATERAL ENDOPHTHALMITIS

ISBCS has not gained traction in the United States to the same degree that it has internationally. US reimbursement rules impose significant financial disincentives on surgeons with regard to operating on both eyes on the same day. Another obstacle is surgeons' fear of simultaneous bilateral endophthalmitis or bilateral toxic anterior segment syndrome. Arshinoff and Bastianelli reported that, from 1950 to the present, four cases of simultaneous bilateral endophthalmitis have been published; all of these cases involved a breach in aseptic protocol.[4] Their literature search revealed that, in recently published European studies on prophylactic intracameral cephalosporin, the incidence of postoperative endophthalmitis after unilateral cataract surgery weight-averaged to one in 331 (0.3%) without prophylactic intracameral antibiotics and to one in 1,977 (0.05%) with prophylactic intracameral

antibiotics. In comparison, studies conducted in the United States using only topical antibiotics report infection rates as low as 0.028%. Extrapolating from data from the intracameral antibiotic arm, Arshinoff and Bastianelli calculated that the risk of simultaneous bilateral endophthalmitis after ISBCS would approach 1:100 million patients.[4]

Data collected from members of the International Society of Bilateral Cataract Surgeons show that no instances of bilateral simultaneous endophthalmitis occurred in 95,606 cases of ISBCS. The overall rate of endophthalmitis after cataract surgery on one eye was one in 5,759 cases, and infection rates were significantly reduced with intracameral antibiotics to one in 14,352 cases.[4]

BILATERAL REFRACTIVE LENS EXCHANGE

Given the recently rapid progress in modern lens surgery techniques, should we be open to performing same-day bilateral lens surgery? I would argue yes if scientific data can show that it is safe and adds value to patients' experiences.

Jonathan Christenbury, MD, has the best-documented series of same-day bilateral refractive lens exchange (RLE) in the United States.2 In 2005, Dr. Christenbury implanted the AcrySof IQ Restor IOL (Alcon Laboratories, Inc.) in both eyes of his patients 1 to 2 weeks apart. They complained during the period between surgeries of difficulty with the disparity in image quality between their eyes. Between 2006 and 2007, Dr. Christenbury performed bilateral lens implantation 1 day apart in 1,006 eyes. His patients reported greater satisfaction with the procedure, mainly because their eyes came to work together more quickly. A common complaint, however, regarded the inconvenience of undergoing surgery on 2 consecutive days. In response, Dr. Christenbury issued a new consent form that allowed patients to opt for same-day bilateral RLE. Each eye was treated as a separate procedure with different equipment and preparation. Ninety percent of his eligible patients chose same-

day bilateral RLE, and from this cohort of more than 1,000 patients, he has reported zero cases of endophthalmitis or toxic anterior segment syndrome. The only complication he has reported is capsular rupture in two cases. In both, the complication affected the second eye in sequence and resulted in no vision loss.[2]

CONCLUSION

My primary purpose in writing this article is to stimulate discussion about same-day bilateral RLE. When LASIK was first introduced, we waited 6 months between procedures on the right and left eyes. As supportive data became available, the time between surgeries decreased to 3 months and then 1 week before same-day bilateral procedures became the norm. I believe that lens surgery will follow a similar progression.

My colleagues and I are not currently performing same-day bilateral RLE in our practice. We have incorporated premium IOLs and laser cataract surgery, however, and are considering whether to move some of our lens surgery to the office's refractive suite in the next few years. Same-day bilateral RLE represents a natural step in the progression of premium services we offer to patients. We will only take this step, however, if scientific data prove it to be safe. As lens surgery evolves, patients' safety remains the indisputable sine qua non.

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HUMANITARIAN OUTREACH | APR 2012

LDS Charities Aims to Empower Local Doctors

Patients in Mongolia now have access to vitreoretinal services.

Roger P. Harrie, MD

Latter-day Saint (LDS) Charities has been active in various types of sight-saving projects throughout the world since 2003. Programs have ranged from providing automated lens grinders for opticians to making glasses for school children to sponsoring a fellowship in vitreoretinal surgery. It is estimated that more than 550,000 people have benefited from these services in approximately 47 countries. Ocular health outreach projects are scheduled in more than 30 countries this year.

The basic principle of all of this outreach is to empower local ophthalmologists to provide care to the people of their respective countries with an emphasis on helping underserved individuals.

An assessment team meets with doctors, hospital administrators, and governmental health officials to assess the host country's needs and resources within its vision care system. The team reports back to the LDS Charities' board and proposes a project with a budget for training, equipment, and supplies. The fundamental goals of each project are directed toward sustainability. An example of this approach is illustrated by a recent project in Mongolia.

MONGOLIAN PROJECT

Chimgee Chuluunkhuu, MD, and her husband Boyan practice ophthalmology in Mongolia's capital city of Ulaanbaatar. They have been active in outreach programs for a number of years. They load their portable microscope and cataract instruments into their SUV and travel hundreds of miles in the -40º F temperatures of the Mongolian winter. They will spend a few days in an *aimag* or local province to provide diagnoses and treatments, including cataract surgery, to the people of that area. Boyan has been known to take his rifle with him and do some hunting along the way. The couple works out of a small two-room clinic and do their best to help people using the basic pieces of dated equipment that they have.

Chimgee has been active with a national group that coordinates various nongovernmental organizations within her country. Through this experience, she recognized the need for a systematic approach to the diagnosis and treatment of diabetic retinopathy in Mongolia. She completed a master's program in epidemiology at the London School of Hygiene & Tropical Medicine. For her master's thesis, she investigated the prevalence of diabetic retinopathy both in the capital city and in several *aimags*. LDS Charities

provided her with a fundus camera with the capacity for fluorescein angiography to document retinopathy.

PREVALENCE OF DIABETIC RETINOPATHY

Phase 1

In her research, Chimgee found that diabetic retinopathy was present in about one-third of those with diabetes, and sight-threatening retinopathy was found in more than 6% of them. More than 96% of those with potentially treatable retinopathy (laser or vitrectomy candidates) had not been treated. At that time, in 2010, there was only one argon laser in Mongolia, and it was located at a private clinic with limited accessibility. No vitreoretinal surgery was being performed in the country.

Phase 2

The next phase of the project was to provide a solidstate green laser to the Chuluunkhuu's clinic and one to a government hospital to increase the country's capacity to treat retinopathy. A training team was sent to Mongolia with two suitcase-sized lasers in hand. The lasers were assembled, physicians were trained on how to operate them, and the first patients were treated. During the same week, ophthalmologists from a number of *aimags* were invited to a 3-day conference to learn how to diagnose diabetic retinopathy. The symposium included a lecture series directed by a US ophthalmologist in conjunction with Chimgee and hands-on workshops on the use of the direct ophthalmoscope and the +90.00 D lens. The fundus camera was incorporated into the workshop. Participants then used the +90.00 D lenses to visualize the same fundus and reinforce what they had seen. Each participant was then given an ophthalmoscope and a +90.00 D lens to take back to his or her own clinic.

Phase 3

The third phase of this project is the selection of an ophthalmologist from Mongolia, Tsengenbayar Munkhzaya, MD, who is currently receiving

vitreoretinal training at the L V Prasad Eye Hospital in Andhra Pradesh, India. This will consist of a 15-month surgical fellowship after which he will return to Mongolia to begin treating patients with all types of retinal problems, including those resulting from diabetic retinopathy. There are currently no vitreoretinal surgeons in Mongolia, and most patients cannot afford to leave the country for treatment. Several retinal surgeons from the United States will then go to Mongolia on a 2-week rotating basis to work with Dr. Munkhzaya to reinforce what he has learned and address the backlog of retinal cases. When completed, this multiphased project will have a major impact on the diagnosis and treatment of retinal disease in Mongolia.

EGYPT

Another project directed toward the recipients' becoming self-sufficient has recently been completed in Egypt. A family of ophthalmologists headed by Said Saif, MD, of Cairo has been actively involved in charitable campaigns for more than 45 years. The following are examples:

- An Oasis campaign conducted once yearly for 6 to 9 days; 19,000 patients are examined, and 350 major operations and 1,500 minor operations are performed.
- The Fayed campaign conducted on the first Friday of each month; 600 to 800 patients are examined, and 20 major operations and 30 minor operations are performed.
- The Baharia Oasis campaign is conducted four times per year for 2 days; 3,000 to 3,500 patients are examined, and 30 to 40 major operations and 150 to 200 minor operations are performed.
- A campaign in Cairo is conducted in different locations on the third Friday of each month for 1 day; 600 to 800 patients are examined and 60 to 80 major operations and 45 to 60 minor operations are performed.
- The Fayoum campaign is held once a month on the fourth Friday of each month for 1 day; 1,100 to 1,400 patients are examined, and 20 major operations and 45 to 60 minor operations are performed.

LDS charities has worked with the Saifs' foundation during the past 10 years and has donated supplies and equipment and provided training. Sadly, Dr. Saif passed away 2 years ago, but the family has carried on his humanitarian work for the people of Egypt.

In 2009, LDS Charities donated an ophthalmic diagnostic ultrasound unit to the group and sponsored an observership in ultrasound at the Wilmer Eye Institute at Johns Hopkins in Baltimore. Passant Saif, MD, has been trained in the United States and has returned to Egypt where she plans to establish an ultrasound department at the hospital where she teaches and also at the Saifs' clinic. Patients who can afford to pay will be charged a fee, which will go toward subsidizing the outreach campaigns. Patients who cannot afford to pay for their surgery are treated free of charge.

OTHER OUTREACH

LDS Charities is also involved in providing aid to people affected by emergencies such as the Japanese tsunami. In 2010, relief in the form of volunteers and supplies was provided in response to 119 disasters in 58 countries. Immunization projects have been estimated to have saved 9.3 million lives since 2003. Wheelchairs have been distributed to 415,000 individuals since 2002. More than 190,000 health professionals have been trained in neonatal resuscitation techniques in a number of developing countries during the past 9 years, and 7.5 million people now have access to clean water due to projects during that time. Food-production techniques have been taught to 40,000 people.[1]

CONCLUSION

The fundamental goal of helping people throughout the world to become self-sufficient is the principle on which LDS Charities bases its humanitarian efforts.

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1. The Church of Jesus Christ of Latter-Day Saints. Humanitarian projects. http://lds.org/service/humanitarian/ church?lang=eng&lang/=eng. Accessed December 20, 2011.

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TODAY'S PRACTICE SOCIAL EYES | APR 2012

Paging Dr. Blogger: Tips for a Successful Health Care Blog

An engaging, informative health care blog can help physicians connect with patients and establish themselves as leaders in their profession.

Cary M. Silverman, MD, MBA, and Shama Kabani

You have decided to start a health care blog. That's great! Publishing a blog can be one of the most effective ways to build an online community. How do you get started?

No. 1. Define your goals

Before you start a blog, define what you expect to gain from the endeavor. Maybe you want to land new patients, reconnect with existing patients, or increase their awareness of your presence in the medical community. Whatever your goal, do not start a blog because you think you need to have one. A blog should have a definite purpose from the beginning. What would you like to have gained in 3 months? Six months? A year?

No. 2. Write for your audience

A blog targeted to patients will read much differently than a blog targeted to other doctors. Your patients are not only looking for easily accessible, quality information; they are looking to fully understand that information. It is safe to assume that the majority of your patients have not been to medical school and therefore do not speak “Doctorese.” Explain yourself in layman's terms, especially if the medical concepts you are discussing are complex or full of Latin words. Be warm and friendly, and do not be afraid to craft a unique voice for yourself.

No. 3. Post regularly

Updating your blog regularly with fresh, engaging content is key to keeping readers interested. Post new entries once a week at the absolute minimum. Readers expect blogs to be full of timely, relevant content. A blog that has not been updated in months reflects more poorly on you than not having a blog at all, because it looks like you gave up or forgot about it altogether. If you do not think you are up to the commitment, consider outsourcing your practice's marketing duties or hiring a blogger.

No. 4. Avoid direct PUBLIC RELATIONS/ marketing tactics

The primary purpose of your blog should be to educate and inform. Yes, your blog should display your knowledge of and expertise on the subject matter you are discussing. If you try to overtly “sell” yourself, people are going to tune you out. Your readers are already bombarded by advertisements online, in movies, and on TV, billboards, buses, and the radio. If your blog contains valuable, high-quality content, you are selling yourself better than any advertisement or public relations pitch ever could.

No. 5. Engage in conversations and build relatio