

The Fine View: Summer 2008

The Drug-Device-Doctor Dilemma

By Dr. I. Howard Fine



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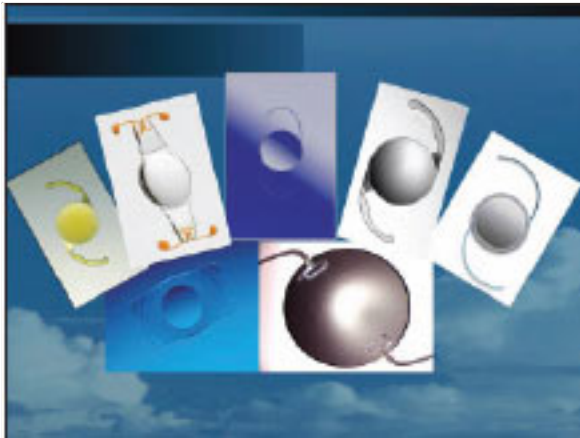


Tina Callina, COMT, CRCC

There has recently been a great deal of publicity surrounding the relationship between drug companies, device manufacturers, and doctors that suggests the possibility of a compromise in optimum patient care. Our own local newspaper had a front-page article in a recent Sunday edition disparaging the relationship of the drug industry with the medical profession and suggested that simple gifts, such as ballpoint pens or coffee mugs, and the availability of samples for physicians to give to their patients, have had a detrimental effect on practice patterns. We view this as ludicrous and recognize that drug samples allow us to reduce costs for patients when we are initiating a change in their therapy.

There has been, since medicine began, an ongoing evolution in medical and surgical modalities. Among the most obvious examples is the development of antibiotics, which occurred early in the Second World War, resulting in a dramatic

decline in deaths from infectious diseases. During the Civil War, there were two types of wounds described by medical personnel: mortal wounds, which were body and head wounds that could not be treated; and limb wounds, which were treatable only by amputation. Today there are enormously sophisticated surgical modalities for treating body and head injuries. The relief of pain through medication is a relatively recent development and has eliminated one of the most dehumanizing experiences people can face.



Intraocular lenses (IOLs) are devices that must undergo FDA-monitored clinical trials to be approved, and are routinely used by cataract surgeons.

Clinical research is investigational and it follows a long process of initial laboratory, then animal studies. Only after laboratory and animal studies have documented safety and efficacy are human clinical trials commenced. A clinical trial is a research study involving human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work and ways to improve health.

There are multiple built-in protections for human patients who participate in clinical trials. The Food and Drug Administration (FDA) monitors most of these studies, as do Institutional Review Boards (IRBs), which check every aspect of the proposed study, including informed consent documents for patients, data gathering, and any side effects over a period of several years. Initial studies involve a small number of patients, with increasing numbers in subsequent studies, as the safety and efficacy of the treatment appears to be confirmed. After exhaustive studies and follow-up over several years, the new drugs or devices are approved for routine use.

Innovation in medical therapy requires industry. There is no way an idea for a treatment that can alleviate suffering, enhance healing, or improve human function can come to the market place without industry to underwrite the cost of the

development of the idea, the manufacture of the drug or device, the cost of the clinical trials, and the enormous expense of traversing the regulatory environment that the FDA has established.

Our participation in clinical research is one of the unique aspects of our practice. We have participated in 55 different clinical research projects, most of which have been monitored by the FDA, and are currently involved in 17 additional projects. Those projects include every aspect of cataract surgery, from incisions to pharmaceuticals and injectables used at the time of surgery, to the multiple instruments and various technologies utilized during the surgery, the design and implantation of intraocular lenses, incision closure, and new, innovative ways to address post-operative care. We also participate in refractive surgery studies for new or enhanced methods for vision correction. We limit our investigational activities to modalities and devices that appear to have great advantages for patients and no foreseeable disadvantages.

Our investigational studies, and our participation in 30 different scientific advisory boards, have resulted in 22 new and innovative surgical techniques, the development of 40 new surgical instruments, the publication by us of over 600 scientific journal articles, and more than 1,000 presentations all over the world on the use of these new therapeutic modalities. Much of what we have developed in our practice has become the standard of care world-wide, and has resulted in greater surgical safety, less invasive surgery, enhanced outcomes, more rapid visual rehabilitation, decreased dependence on spectacles, and a dramatic reduction in the cost of cataract surgery. We never participate in any study in which the risks have any likelihood of outweighing the potential benefits.

The question is, are we bought or compromised? Is patient care adversely affected by these activities? Our mission statement is as follows: We are committed to providing the most technologically advanced, cost-effective patient care, with the highest quality of professionalism. We must be involved in clinical research to provide the most technologically advanced care to our patients. As a result of these research activities, our patients have access to technology five to seven years before it is generally available to all patients, and they benefit from the advantages of this new technology. We value our relationship with industry because we learn from each other and partner with them in clinical research. The bottom line for us is improving the state of the art and science of eye surgery, and we know that the patients are the main beneficiaries of these activities.

Our mission statement is the mantra by which we live and practice. It is important for patients to understand the partnership between the medical profession and industry is a necessary and important one, and we are always aware of potential conflicts of interest. Clinical trials are a critical tool for determining which

preventive, diagnostic, and/or therapeutic interventions have value, compared to alternative treatments. They are designed to ensure maximum patient protection and safety. Nothing has ever compromised our interest in providing the best medical and surgical care for our patients.

Life Changing Events **By Richard S. Hoffman, MD**



Richard S. Hoffman, M.D.

The longer I practice ophthalmology, the more I am amazed at how simple preventable accidents can result in severe visual loss. Sometimes the difference between a scar and complete blindness can be a few millimeters.

Take Joe for instance. Joe was cutting firewood with a chainsaw when the saw stuttered and flew back into his face. The saw cut through the skin of his forehead, creasing the bone, and cut through his upper eyelid and cheek. Miraculously, the wound did not penetrate into his eyeball. A few millimeters deeper and he would have been blind in that eye but he got away with a long scar and perfect vision.



Now let's take John. John was hammering a nail without safety glasses. Not a smart thing to do by the way. A small piece of metal about the size of a pinhead flew off of the nail – the result of hammering metal upon metal – traveled through his eye and lodged in his retina in the exact location that is responsible for sharp central vision. He was blinded despite surgery to remove the metal from his eye and treat the traumatic cataract that resulted from the injury.

These injuries impress me with how precious and precarious our vision truly can be. A pair of safety glasses worn at the right time could have made the difference between blindness and an incidental event that would have never even been appreciated. Other frequent injuries we see include trauma from soccer balls, racquetball and racquets, paintballs, rocks being thrown up from lawnmowers and weedwackers, fireworks, and perhaps one of the most devastating injuries – bungee cords.



Bungee cords are frequently used to fasten luggage to cars or bicycles. They are ubiquitous in our society and perhaps one of the most frequent and unknown

causes for severe visual loss. I have seen at least three or more incidents of bungee cords breaking or coming loose during the stretching maneuver resulting in the cord or metal hook flying back into the eye with serious consequences. I have never seen anyone traumatized from a bungee cord that did not have severe visual loss or blindness. If you use bungee cords, make sure that you are not pulling the cord towards yourself. Think about which direction the cord would strike if the metal hook came off or the cord broke and place yourself in a safe position away from that direction. Better yet, don't use them.

No one expects to get injured or cause an injury while using a bungee cord or hammering a nail but when it happens, it is truly tragic because it could have been avoided with a little strategic planning or a simple pair of safety glasses. Educating the public to some of these potential injuries may help avoid a life changing event.

Honors and Awards **By Sherrie Brunell, MS**

The entire Drs. Fine, Hoffman and Packer team made an impressive showing at the annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS), in Chicago this year. ASCRS is an independent non-profit organization founded in August of 1974 to disseminate information about anterior segment ophthalmic surgery. Their annual meeting is one of the largest ophthalmic meetings of the year. Our doctors gave over 35 lectures and taught in multiple courses on topics ranging from LASIK flaps, the challenge of small pupils in cataract surgery, multifocal and accommodative intraocular lenses (IOLs), wavefront technology, and that was just the beginning.

Dr. Hoffman's video on "Scleral Fixation without Conjunctival Dissection" won first prize in the "New Techniques" category of the ASCRS Film Festival. This video has been very popular with physicians around the world and is considered to be an outstanding teaching video. In addition to the video award, Dr. Hoffman's paper on "Persistent LASIK Interface Fluid Treated by Flap Elevation" won Best Paper of Session in Session 4-B: Keratorefractive Nomograms, Outcomes, Technology.

Dr. Fine and Laurie Brown, COMT, COE, our practice administrator, were honored to help design and participate in the first joint course of the American Society of Ophthalmic Administrators (ASOA) and the ASCRS on "Practice Management Pearls: The Physician-Administrator Team." Dr. Fine gave the opening statement on the importance of a good and trusted practice administrator in developing a physician's goals for his or her practice, and both participated in the panel discussion. The course was well received by both physicians and administrators.

Last, but certainly not least at ASCRS, Laurie Brown, and Jon Cassidy, one of our ophthalmic technicians, were delighted when the poster on implementing EMR, “EMR: Steps for Success – A Case Study,” that they helped to create also won first place in their category. This poster was produced in conjunction with other members of the Oregon Eye Associates team, Charity Duckett, Jaime Maldonado, Kay Mellenthin, and Joy Woodke, and it outlined our experience of choosing and implementing an electronic medical records (EMR) system throughout our entire building.

Dr. Packer achieved his ten-year recertification from the American Board of Ophthalmology (2008 – 2017). He was selected as the American Academy of Ophthalmology Council Pacific Regional Subspecialty Co-Chair for 2008, and was named Peer Reviewer for the journals Clinical & Experimental Ophthalmology and The American Journal of Case Reports.

Congratulations to all!

New Faces



Katie Frank, who is a recent graduate of the University of Oregon, is the newest addition to our team. She feels the field of ophthalmology is unique because it gives her the opportunity to learn and grow while changing lives. Katie enjoys athletic activities as well as spending time with close friends and family, and is excited to be a part of our unique practice.

Testimonials



Having LASIK surgery on my eyes was something I had wanted to do, but I was extremely nervous about the prospect of using a laser to correct my vision. During the procedure my entire body was clenched! Dr. Fine's son, Edward, held my hand and was very comforting. Laurie spoke soothingly and described in detail what was happening. Dr. Fine's expert hands were steady. The entire surgery lasted only minutes, and then I was amazed that I was able to see immediately! Things were blurry, but it felt like I was wearing contacts and they were dry.

After the procedure, I experienced some burning, but that went away within a few hours. Less than six months later, I tend to forget that I have had anything done. My vision is incredible! My vision is comparable to wearing contacts; I am able to read very well, and my distance vision is also phenomenal. I am so happy that I decided to go through with the surgery, and I especially enjoy being able to see clearly first thing in the morning and to not have to deal with the hassle of wearing contacts any more.

I would recommend Dr. Fine and his staff to anyone who is considering having their vision corrected. You could not find a more caring staff or brilliant doctor!
Thank you! Margie Van Dorn



Boyd Steele, cataract patient who had ReZoom lenses implanted by Dr. Fine.

My distance and near vision are very good. In some ways it's better than it ever has been. I can see up close when using the site on my rifle or gun and I see the target very clearly. I'm overwhelmed with the three dimensional effect. My depth perception is really good and colors are so much brighter. I had virtually no vision before surgery without glasses and now I can see everything.

Drs. Fine, Hoffman, & Packer Travel/Teaching Schedule — January through May 8, 2008

January 12-13: Atlantic City, NJ

Dr. Hoffman was the invited guest speaker at the State University of New York (SUNY) Downstate Medical Center Current Concepts in Ophthalmology meeting. Dr. Hoffman spoke on refractive lens exchange, accommodative IOLs, and the implantable collamer lens.

January 21-25: Waikoloa, HI

Dr. Packer and Laurie Brown, COMT, COE, participated in the Hawaiian Eye Meeting, sponsored by the Royal Hawaiian Eye Foundation and Slack, Incorporated. Dr. Packer gave lectures on topics such as aspheric IOLs and refractive lens exchange. Dr. Packer and Ms. Brown gave a presentation on, "New Technology IOLs: What We've Learned," at the administrators' portion of the meeting.

January 24-26: Park City, UT

Dr. Fine participated in the New Techniques & Controversies in Cataract and Refractive Surgery meeting, sponsored by Alcon Laboratories and the Dulaney Foundation. Dr. Fine addressed such topics as phacoemulsification in the presence of shallow anterior chambers and small pupils, and a new technique for the implantation of capsular tension rings.

February 3-8: Cancun, Mexico

Dr. Packer participated in the American Society of Cataract and Refractive Surgery (ASCRS) Winter Update meeting. He gave presentations on refractive lens exchange, refractive and phakic IOLs, and advances in phacoemulsification technology.

February 15-16: Milan, Italy

Drs. Fine and Packer were invited to participate in the Video Catarattarefrattiva competition via DVD uploaded onto the world-wide web. Dr. Fine's entry, "Every Small Pupil Must Be Viewed as a Potential IFIS," won first prize in the Challenging Cataract category.

April 4-8: Chicago, IL

The entire practice was an impressive force at the annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS). Drs. Fine, Hoffman and Packer gave multiple lectures and taught several courses on such topics as phacoemulsification in difficult and challenging cases, biaxial microincision phacoemulsification, IOL optics, and presbyopia-correcting IOLs. Dr. Hoffman's submission to the video competition won first prize in his category, and his paper won Best of Session. In addition, the poster on implementing EMR that our practice completed in conjunction with other members of the Oregon Eye Associates team also won first place. See Honors and Awards for more details.

April 9-11: Washington, DC

Dr. Packer participated in the annual mid-year forum of the American Academy of Ophthalmology. Dr. Packer represents the American Society of Cataract & Refractive Surgery on the Council of the American Academy of Ophthalmology. Important topics at this year's meeting included Conflict of Interest and Access to Care.

May 9-10: Naples, Italy

Dr. Fine was honored to give the annual Benedetto Strampelli Medal Lecture at the 13th Annual International Joint Meeting of Ocular Surgery News, Italian Society of Ophthalmology and the Italian Association of Cataract and Refractive Surgery. Dr. Fine spoke on phacoemulsification in difficult and challenging cases.