

MASTERING REFRACTIVE IOLs: THE ART AND SCIENCE

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Dedication



From l to r: Drs. Geoff Tabin, R. D. Ravindran, David F. Chang, and Sanduk Ruit.

This textbook highlights the latest advances in refractive IOL technology and surgery. No longer satisfied with simply treating cataracts, our efforts are now focused on reversing lens aging through the pseudophakic correction of presbyopia. Amidst such exciting advances, it is easy to forget that the greatest challenge in the field of cataract and IOL surgery continues to be the staggering and increasing backlog of cataract blindness in developing countries.

Modern phacoemulsification machines are expensive to purchase and maintain, incur relatively high disposable costs, and require extensive surgical training. Furthermore, for the more advanced and mature cataracts typical of underserved populations, performing phacoemulsification becomes more difficult and complication prone. What is needed is a high-volume, cost-effective, “low tech” procedure that can treat the most advanced of cataracts with a low complication rate in the shortest amount of time.

This very goal is being achieved in a handful of international programs that are providing a hopeful paradigm for overcoming cataract blindness worldwide. I have had the privilege of visiting and collaborating with doctors at both the Aravind Eye Hospital network in Southern India, and the Tilganga Eye Center in Kathmandu, Nepal. Observing first-hand how these 2 systems provide low-cost, high-volume and quality cataract surgery is an awe-inspiring experience for any visiting ophthalmologist.

Founded in 1976 by the legendary Dr. G. Venkataswamy, Aravind Eye Hospital has grown into a network of 5 regional eye hospitals providing high-level ophthalmic care to the poor population of Southern India. Private paying patients comprise approximately 30% of their patient base. This revenue funds the 70% of Aravind’s services that are provided at no cost to the indigent via a financially self-sustaining program that receives minimal government reimbursement. In terms of cataract surgery, this means that of the approximately 200,000 procedures performed annually in the Aravind system, 70% are provided for free.

While private cataract patients at Aravind may pay anywhere from \$200 to \$300 to undergo phacoemulsification with foldable IOLs imported from the United States, the nonpaying cataract patients are treated for less than \$15 per case, including the IOL. This is accomplished by performing a manual, sutureless, small incision extracapsular procedure with reusable equipment and supplies. Their IOL manufacturing facility, Aurolab, produces PMMA IOLs for less than \$5 per lens. Following a retrobulbar block, the nucleus is expressed through a capsulorrhexis and a temporal, self-sealing 6.0- to 6.5-mm scleral pocket incision. Manual cortical cleanup precedes capsular bag implantation of a square edge PMMA IOL. The technique is commonly abbreviated as manual SICS (small incision cataract surgery).

While the procedure itself seems straightforward, it is the stunning speed, skill, and efficiency with which it is performed that must literally be seen to be believed. By alternating between 2 parallel operating room tables, a single surgeon is able to perform over 15 cases per hour by consistently completing sub-5-minute procedures on the densest of cataracts with no intervening turn-over time. To ensure efficiency across different surgical teams, every aspect of the procedure is standardized, from preoperative patient and instrument preparation to the surgical steps themselves. Having been screened in outlying rural eye camps, as many as 300 to 400 cataract patients will be bused to a regional Aravind eye hospital where they will all undergo their surgery on one single day. After several days of in-house follow-up, they are transported back to their rural villages where a local postoperative visit and refraction are performed 1 month later by the Aravind staff.

Founded in 1994 by Dr. Sanduk Ruit, the Tilganga Eye Center is a shining example of an efficient eye care delivery system on a smaller scale. Dr. Ruit has developed his own variation of the manual, sutureless SICS. Our prospective randomized trial comparing phaco and manual, sutureless SICS in a camp population showed that the latter method produces excellent results at

a fraction of the cost.¹ Tilganga Eye Center is also financially self-sustaining wherein private care subsidizes charity care. They also have their own IOL manufacturing facility, which, like that at Aravind, is able to supply low-cost IOLs to other developing countries. Because the rural population in Nepal is so widely scattered amongst mountain villages that are accessible only by foot, the Tilganga system strives to deliver portable cataract care by transporting the necessary staff and equipment to remote eye camps. Using a single portable operating table, the Tilganga surgeons can also perform more than 10 cataract surgeries per hour. As at Aravind, the high-volume, cost-effective Tilganga surgical techniques and protocols are standardized across their surgical teams. Since 1994 when Dr. Ruit and Dr. Geoff Tabin co-founded the Himalayan Cataract Project, Tilganga ophthalmologists and staff have provided mobile cataract surgical care and physician training in numerous developing countries across mountainous Asia.

Though of a different scale and serving different types of communities, Aravind and Tilganga are complimentary models of how best to address the world's backlog of cataract blindness. They demonstrate that the solution requires not only a cost-effective surgical technique, but also an entire system of efficient and financially self-sustaining cataract care delivery. Beyond the impressive productivity of these 2 institutions, equally important has been their mission to train surgical teams from other developing countries in their methods of cataract surgery. An efficient, high-volume system utilizing low cost, sub-5-minute procedures to tackle advanced cataracts with minimal complications is clearly the best way to leverage the scarcest and most precious asset of the system—the cataract surgeon.

I consider this work to be the most inspiring and impressive accomplishment in our field of cataract surgery and it is with great respect and admiration that I dedicate this textbook to my friends at the Aravind and Tilganga Eye Hospitals. They are the unsung but true heroes in our field, and as we struggle to meet the high refractive expectations of our premium IOL patients, we must remember and salute our colleagues in developing countries that are on the frontlines of the most important surgical battlefield.

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Acknowledgments

Compiling this textbook was a colossal venture and adventure that was completed in record time. I first approached SLACK Incorporated with the idea during the 2007 ASCRS meeting where, judging from attendance at symposia and instruction courses, interest in refractive IOLs was rising along a steep trajectory. The need for more physician-to-physician education on the subject was very obvious. However, whether it was a symposium, instruction course, booth presentation, or users meeting, there was always far too much material to cover in the available time. So many of the pearls I learned were beyond the realm of evidence-based medicine. Where could all of this information be found or collected? Recognizing the pressing and unmet need for a comprehensive textbook, we established the ambitious goal of completing this book in time for the 2008 ASCRS meeting—a 9-month publishing cycle.

My initial plan was to assemble a manual for transitioning to refractive IOLs. So many colleagues have yet to embark on this odyssey and the number of hurdles for the beginning refractive IOL surgeon is daunting. It soon became obvious, however, that the educational process is far more than a series of “transitioning” steps because there really is no endpoint. Regardless of our experience, we are all continually learning new insights and approaches in our quest to improve. What began as a modest beginner’s manual therefore morphed into a comprehensive 236-chapter textbook on mastering the multidisciplinary and multidimensional skills necessary for success as a refractive IOL surgeon.

I am truly grateful to my 4 associate editors, Steven J. Dell, Warren E. Hill, Richard L. Lindstrom, and Kevin L. Waltz, each of whom is among the most influential innovators, opinion leaders, and educators in the refractive IOL field. Whether as authors, editors, or as a collective sounding board for selecting topics and authors, their influence and guidance is evident throughout the book. I have enjoyed creating a lasting testament to our collaboration and friendship.

I particularly want to thank the more than 200 authors who have written original chapters for this textbook. To possess the expertise that makes each of them an effective teacher means that they are all very busy clinicians. Writing and illustrating chapters during weekends under tight deadlines is a thankless job. I hope you readers appreciate the generosity of their time in sharing their personal experiences and lessons with you.

Finally, this was a project that put SLACK Incorporated’s fine Book Division to the ultimate test. I am fortunate to have such an excellent working relationship with John Bond and Jennifer Briggs, who gave me the freedom and flexibility to steer this, our third textbook project, in the direction that I wanted. They are truly dedicated professionals who managed the entire process from pilot concept to final deadline. With the support of Managing Editor, Kimberly Shigo, Senior Project Editor, April Billick, turned in another unbelievable job with the layout and the editing process. Managing so much material from so many authors under such tight deadlines is a testament to April’s organizational skills and excellence as an editor. That I would even consider undertaking such an ambitious project is a measure of my respect and high regard for the SLACK Incorporated team.

Finally, writing on behalf of my 4 associate editors and our more than 200 coauthors, we would like to thank our families for allowing us to devote our precious time and energy toward compiling a resource that we hope will help all refractive IOL surgeons and their patients worldwide.

David F. Chang, MD

About the Chief Editor



David F. Chang, MD is a Summa Cum Laude graduate of Harvard College and earned his M.D. at Harvard Medical School. He completed his ophthalmology residency at the University of California, San Francisco (UCSF) where he is now a clinical professor. Dr. Chang is Chairman of the American Academy of Ophthalmology (AAO) Annual Meeting Program Committee, having previously chaired the Cataract Program Subcommittee. He organized and was the program cochair for the first 7 AAO "Spotlight on Cataracts" Symposia. He is also on the program committees for the ASCRS Annual Meeting and the OSN Hawaiian Eye Meeting.

He has been selected to deliver the following named lectures: Transamerica Lecture (UCSF), Williams Lecture (UCSF), Wolfe Lecture (University of Iowa), DeVoe Lecture (Columbia-Harkness), Gettes Lecture (Wills Eye Hospital), Helen Keller Lecture (University of Alabama), Kayes Lecture (University of Washington, St. Louis), Thorpe Lecture (Pittsburgh Ophthalmology Society), Schutz Lecture (New York University Medical Center), Wallace-Evan Lecture (Casey Eye, Oregon), Proctor Lecture (UCSF/Proctor Foundation), and the keynote address at the Chinese American Ophthalmological Society's 20th anniversary meeting. He is a 3-time AAO Secretariat Award recipient (2003, 2006, 2007). He was the inaugural recipient of the UCSF Department of Ophthalmology's Distinguished Alumni Award (2005) and in 2006 became only the third ophthalmologist to ever receive the Charlotte Baer Award honoring the outstanding clinical faculty member at the UCSF Medical School. He was the third recipient of the Strampelli Medal from the Italian Ophthalmological Society (2007).

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About the Associate Editors



Steven J. Dell, MD is Medical Director of Dell Laser Consultants and Director of Refractive and Corneal Surgery at Texan Eye in Austin, Texas. He serves on the Refractive Surgery Clinical Committee of the American Society of Cataract and Refractive Surgery and is a popular lecturer at meetings worldwide. He is the inventor of several popular surgical instruments and medical devices. Dr. Dell serves on the editorial boards of *Ocular Surgery News*, *Cataract and Refractive Surgery Today*, *The Video Journal of Ophthalmology*, and *Cataract and Refractive Surgery Today—Europe*. Dr. Dell is a board-certified member of the American Board of Ophthalmology, a Fellow of the American Academy of Ophthalmology, and a member of the American Society of Cataract and Refractive Surgery. He works closely with a variety of ophthalmic companies in the development of new products and technologies and serves as a consultant to several major companies in the industry.



Warren E. Hill, MD has served as the Medical Director of East Valley Ophthalmology in Mesa, Arizona for the past 22 years, specializing in consultative ophthalmology, challenging anterior segment surgery and intraocular lens power calculations.

Dr. Hill received BS and BA undergraduate degrees at the University of Maryland, a Doctor of Medicine from the University of Arizona, and completed an ophthalmology residency at the University of Rochester, in Rochester, New York. Dr. Hill is also a member of the International Intra-Ocular Implant Club, a Fellow of the American College of Surgeons, the American Academy of Ophthalmology, the International College of Surgeons, and the American College of Eye Surgeons.

Dr. Hill has devoted much of his professional activities to the mathematics of intraocular lens power calculations in complex and unusual clinical situations. He is a consultant to industry in the field of intraocular lens mathematics, intraocular lens design, and optical coherence biometry. He has published many scientific articles, served as visiting professor for numerous grand rounds, and has delivered more than 200 presentations to ophthalmic societies in both the United States and internationally in 20 countries and on 6 continents.

Aside from his interest in ophthalmology, Dr. Hill is a multi-engine, instrument-rated commercial pilot.



Richard L. Lindstrom, MD, founder and attending surgeon of Minnesota Eye Consultants and Adjunct Professor Emeritus at the University of Minnesota Department of Ophthalmology, is a board-certified ophthalmologist and internationally recognized leader in corneal, cataract, refractive, and laser surgery. He has been at the forefront of ophthalmology's evolutionary changes throughout his career, as a recognized researcher, teacher, inventor, writer, lecturer, and highly acclaimed physician and surgeon.

After graduating Magna Cum Laude from the College of Liberal Arts at the University of Minnesota, Dr. Lindstrom completed his doctorate degree in medicine in 1972. He conducted research, residency, and fellowship training in cornea at the University of Minnesota and affiliated hospitals and extended his anterior segment surgery fellowship training at Mary Shields Hospital in Dallas and was a Heed Fellow in Glaucoma at University Hospital in Salt Lake City. In 1980, Dr. Lindstrom returned to the University of Minnesota, where he spent 10 years on the faculty of the Department of Ophthalmology, the last two as a full professor and the Harold G. Scheie Research Chair. He continues as Adjunct Professor Emeritus, Chairman of the Vision Foundation, and Associate Director of the Minnesota Lions Eye Bank at the University of Minnesota. He entered private practice in 1989 and has led the growth and expansion of Minnesota Eye Consultants, serving as managing partner for 15 years. He is also medical director of TLC Vision, Midwest Surgical Services, and Refractec. He is Chief Medical Editor of the USA and International editions of *Ocular Surgery News*, which reaches 82,000 ophthalmologists worldwide.

Dr. Lindstrom currently served as President (2007-2008) of the American Society of Cataract and Refractive Surgeons; he also serves on the Executive Committee and is the Chair of the Corporate Gifts Committee for the ASCRS Foundation. He has in the past served as the President of the International Society of Refractive Surgery, the International Intraocular Implant Club, and the International Refractive Surgery Club. He is the Global Education Liaison of the International Society of Refractive Surgery of the American Academy of Ophthalmology.

He is Chairman and CEO of Lindstrom Cleaning and Construction, a three-generation family business. He has endowed funds supporting the University of Minnesota Department of Ophthalmology, the Eye Bank Association of America, and the University of Minnesota Tennis Team.

Dr. Lindstrom holds over 30 patents in ophthalmology and has developed a number of solutions, intraocular lenses, and instruments that are used in clinical practices globally. He serves on the Board of Directors of AcuFocus, Inc, TLC Vision, Occulogix, Eyeonics, Refractec, the Minnesota Medical Foundation, and Inner City Tennis.

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Dr. Lindstrom serves on a number of journal editorial boards, including *Journal of Cataract and Refractive Surgery*, *Journal of Refractive Surgery*, and *Ophthalmic Surgery*. He is the Honorary Editor-in-Chief of the US/Chinese *Journal of Ophthalmology*. He has coedited 7 books, published over 350 peer-reviewed journal articles, and 60 book chapters. His professional affiliations are extensive, including Liaison of the International Society of Refractive Surgery of the American Academy of Ophthalmology.

He is the recipient of numerous awards for distinguished service by national and international ophthalmology associations, including the LANS, Barraquer and the first lifetime achievement award from the International Society of Refractive Surgery in October 1995 and also was honoured with another lifetime achievement award in October 2002, the Binkhorst Lecture Award from the American Society of Cataract and Refractive Surgery, the Bausch and Lomb Lifetime Achievement Award, April 2005, and the Paton Award and NACT from the Eye Bank Association of America.



Kevin L. Waltz, OD, MD was a founding partner of Eye Surgeons of Indiana in Indianapolis in 1993. He has a long-standing interest in refractive surgery as one of the few doctors who was trained in both optometry and ophthalmology. He graduated from the Indiana University School of Optometry in 1981 and the Meharry Medical College in 1987. He completed a 2-year fellowship at the Southern College School of Optometry in 1983. He completed an internship at Vanderbilt University in 1988 and his residency in ophthalmology at the University of Florida in 1991. He completed a 1-year fellowship in ophthalmic plastic and reconstructive surgery in 1992. He was the first ophthalmologist in the world to receive the Array Multifocal IOL as a patient in 1998 and one of the first ophthalmologists in the world to implant the Array in refractive surgery patients. He coined the name PRELEX or presbyopic lens exchange to describe refractive lens surgery. He has taught other doctors from around the world how to successfully incorporate PRELEX into their practice. He first described accommodative arching of the Crystalens in 2004. He remains actively involved in the research and development of surgical eye care.

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Foreword

Ophthalmology is entering an exciting new era. The technology is rapidly changing, our boundaries are expanding, and today every cataract patient can expect to receive an intraocular lens that will not only replace their natural failing lens, but will, in the vast majority of cases, function safely, and at a better optical level, than the lens of a “normal” phakic individual of the same age.

The goal four or five decades ago was to restore useful vision after cataract removal without resorting to thick cataract spectacles; today we are able to provide clarity of vision unequaled even by the natural lens. The rapidly developing field of IOLs began with correction of basic power, then, aided by corneal surgery, astigmatism was conquered. Now a new frontier—presbyopia—has been targeted. In this monumental work, the editors and contributing authors, all active in clinical practice and research, have sought to bring the latest information to the reader. In *Mastering Refractive IOLs: the Art and Science*, Dr. David Chang and his coeditors, along with more than 200 contributors, have provided a comprehensive textbook on the art and science of refractive IOLs for the practicing ophthalmologist.

This new technology will continue to improve, and with it we share the joy, the excitement, and the sheer exhilaration of restoring sight to those who have never been able to see the world clearly. The premium IOL, the presbyopia-correcting IOL, offers a restoration of vision to pre-presbyopic levels with “better than ever” clarity.

Dr. Chang and his associate editors, Dr. Steven J. Dell, Dr. Warren E. Hill, Dr. Richard L. Lindstrom, and Dr. Kevin L. Waltz, present a comprehensive text, designed for surgeons wanting guidance from experts in making presbyopia-correcting IOLs part of their practice.

Covering everything from patient selection and education to management of complications, the text begins with the question, “Why Offer Premium IOLs?” In this section 16 authors share their experience and explain why they have transitioned from monofocal to premium presbyopia-correcting IOLs. Then other experts explain how to select the best IOL for patient needs.

Three things determine the outcome. 1) The patient potential (ie, the visual need and the health of the eye). 2) The technology, and 3) the skill and mind-set of the surgeon. The technology should be determined for the eye, not the eye for the technology. Premium IOLs are not “one size fits all.” The lens should be chosen to meet the patient’s needs and expectations.

It has been said that one who has a watch knows what time it is. If he has 2 watches, he is never sure. Optical characteristics of presbyopia-correcting lenses vary considerably, and the patient’s visual needs factor significantly in the decision of which lens to offer each patient. Each of these lenses has a unique combination of advantages and disadvantages.

Patients are much more interested in the visual outcome than a particular technology, and so the surgeon needs to make decisions that will meet their needs without confusing them with choices that only a scientist can understand. They are more interested in what you tell them about how they will be able to see.

Preoperative education and counseling is critical for success with any presbyopic IOL. Some lessons are clear. One should never promise the patient that he will not need glasses again, but tell him that he will need glasses at least “some of the time.” Then, if he does, you have prepared him and he is satisfied. But if he doesn’t need them, you are his hero.

That we have no universally perfect solution increases the importance of careful patient selection. The premium IOL appropriately allows surgeons to differentiate between refractive surgical goals. Understanding the differences between the available presbyopia IOL designs permits the surgeon to individualize his approach, which for some patients may include mixing different lenses.

This is one of the most thoroughly referenced texts to be published on the science, and the art, of vision correction with IOLs. It is truly a classic. I encourage any serious practitioner of refractive eye surgery to read this book to gain solid instruction in the use of presbyopia-correcting IOLs.

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Preface

Prior to 2004, the distinction between refractive and cataract surgeons was straightforward. Our procedures, reimbursement process, and patient populations were entirely different. All of this changed with the introduction of new presbyopia-correcting IOLs and the landmark Center for Medicare and Medicaid Services (CMS) ruling allowing patients to pay out of pocket for them. Suddenly a major segment of refractive surgery was intraocular, and nearly everyone needing cataract surgery was a potential refractive patient. The following editorial, "A Day to Remember", which I wrote for the June 2005 issue of *Cataract and Refractive Surgery Today*, recalls our initial sense at that time of just how much things were about to change.

In case there was any lingering doubt, recent events have made it official: cataract surgeons are also refractive surgeons. Patients have always wanted spectacle independence, and we've sought all along to reduce the size of incisions and improve biometry in order to approach this goal. However, as a group, we never effectively educated patients and payers about the difference between refractive and medical care for someone with cataracts. AMO's Array and Staar's toric IOLs were the first purely refractive IOL innovations. The new technology intraocular lens (NTIOL) designation for ASC reimbursement made by CMS allowed manufacturers an extra \$50 of reimbursement, but the patient did not pay, nor did the surgeon receive any additional premium for this service. In hindsight, implanting advanced refractive IOL technologies for no additional charge was a mistake, because it diminished their perceived value and made it even harder for patients to differentiate between the capabilities of multifocal and toric IOLs and the benefits of standard cataract surgery. As a result, patient demand for these IOLs became almost nonexistent.

For me, May 10, 2005 (my 25th wedding anniversary), became a doubly memorable date because of the major announcement from the CMS permitting Medicare beneficiaries to choose presbyopia-reducing IOLs at their own expense. By establishing an economic delineation between cataract and refractive IOL technology, this decision is a defining event for us all. With the newsworthy availability of three competing premium technologies to tackle presbyopia (Alcon's ReSTOR, AMO's ReZoom, and Eyeonics' Crystalens), the injustice of denying these options to Medicare patients was averted in the nick of time. That surgeons should receive greater reimbursement to provide these technologies seems clear, as the products do not automatically produce satisfied, spectacle-independent patients by themselves.

Relative to standard cataract surgery, success with refractive IOLs is much more reliant upon an ideal capsulorrhexis and pristine capsular bag, the avoidance of complications, the prevention of surgically induced astigmatism, the reduction of pre-existing astigmatism, and accurate biometry and IOL calculations. Proper patient selection is critical, and physicians must consider patients' ocular and macular health, astigmatism, contralateral refractive error, lifestyle, and personality traits. Patients' expectations and potential for disappointment are much higher with all refractive IOLs and increase pre- and postoperative chair time. In light of these higher demands, the lack of additional reimbursement for NTIOLs was undoubtedly a financial disincentive for many surgeons.

Indeed, hardly anyone noticed or complained when the NTIOL provision officially expired last month. Clearly, achieving a pseudo-accommodating emmetropic eye is a premium refractive service that requires more advanced IOL technology, flawless biometry and surgery, and more extensive patient evaluation and counseling.

Eyeonics blazed a trail with the premium IOL channel whereby non-Medicare cataract patients could pay a fair market, out-of-pocket premium for an uncovered refractive benefit. Thanks to the recent CMS ruling, Medicare patients will enjoy the same freedom of choice. It now behooves us ophthalmologists to properly and ethically educate our cataract patients about the difference between medical and refractive services. When asked what we recommend, we must clarify that refractive IOLs are discretionary—they address the inconvenience of eyeglasses but do not reduce complications or improve ocular health. We must take care not to abuse the economic freedom recently granted to our trusting cataract patients. It is their hard-earned and well-deserved right, and the promising future of refractive IOL technology depends on it.

Today, I think we would all agree that the CMS ruling and the new premium refractive IOLs have dramatically and permanently altered the clinical practice of every cataract and refractive surgeon. Ready or not, we are suddenly faced with the new challenge of educating patients about these multiple options, and then managing and meeting their expectations. Navigating these previously uncharted waters has been both interesting and intimidating, and we are still continually searching for better approaches.

Wouldn't it be wonderful if we could glean the collective wisdom of more than 200 experienced refractive IOL colleagues? This nontraditional textbook seeks to provide such a compendium of practical advice and pearls, reflecting the consensus, controversy, and diversity of our varied opinions, approaches, and practices. To provide as much balance as possible between differing preferences and philosophies, the products and the most important and controversial topics are addressed by multiple different authors.

Refractive IOLs have provided surgeons and patients with exciting new opportunities that also entail different risks and the increased potential for dissatisfaction. For this reason, we must all improve our surgical proficiency, our understanding of clinical



optics, our communication skills, our clinical judgment, and our expertise in avoiding and managing complications. In short, we must all remain committed to mastering both the science and the art of refractive IOL surgery.

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