

ROP: SEEING THE RISK

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Malpractice litigation has had a profound effect not only on the cost of health care but on the practice of medicine – to the point where doctors are reluctant to treat specific diseases. Such is the case with retinopathy of prematurity (ROP).

ROP is a progressive eye disease of the retinal blood vessels occurring in low birth-weight, premature infants. The major physiological risk factors for ROP are low birth weight and early gestational age. ROP can result in severely impaired vision or full blindness. Since it was first described in the medical literature 70 years ago, ROP has increasingly been a source of malpractice litigation against hospitals and pediatric specialists, especially neonatologists and ophthalmologists. In the U.S., the number of premature births since 1981 has risen significantly, and the incidence of this disease has increased along with neonatal survivability.¹

ROP malpractice claims fall into the low frequency/high severity category. Many verdicts and settlements are greater than \$1 million, and some occasionally much higher, including one of \$15 million involving twins in 2001, one of \$20 million in 2006 (that sent shock waves nationwide through pediatric hospitals and other hospitals with Level III Neonatal Intensive Care Units where infants susceptible to ROP are treated) and one of \$38 million in 2008, again involving twins. Like other cases involving children, ROP cases are difficult to defend because of the strong emotions and sympathies they evoke. These cases have a high profile in the legal and medical communities and in the media. Plaintiffs' lawyers seek them out through the internet.² Many ophthalmologists avoid treating these patients due to fear of becoming a defendant in malpractice litigation.³



Picture courtesy of Pediatric Ophthalmic Consultants, New York

This article will review:

- **The physiological risk factors for ROP, clinical presentation and current treatment**
- **Significant barriers to diligent and timely diagnosis**
- **Recent developments in ROP litigation, including primary risk factors and the impact of large verdicts on the health care delivery system and on attending pediatric specialists and hospitals with Level III nurseries**
- **Risk management and patient strategies to prevent the communication errors and systemic problems that often result in litigation**

ROP RISK FACTORS

ROP occurs when premature birth disrupts normal retinal vascular development. The most significant risk factors for ROP are prematurity and low birth weight. The disease does not occur absent these factors.⁴

The risk of ROP is greatest for premature newborns with birth weight of less than 1251 grams and gestational age of less than 31 weeks.⁵ In fact, 80% of premature infants weighing less than 1,000 grams (2.2 pounds) develop the disease, usually in both eyes. The number of premature infants at risk for ROP due to significantly low birth weight has risen since the 1980s as advances in neonatal care have improved infant survival rates. Multiple births due to fertility treatments account for part of the 30% increase in premature births over the last two decades.⁶ But not all premature babies are at risk for ROP, and of those that do develop the disease, about 90% present with a mild case that resolves without therapy.⁷

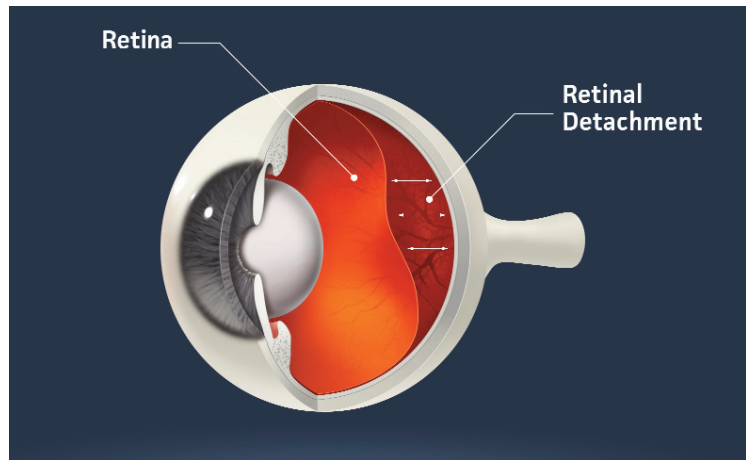
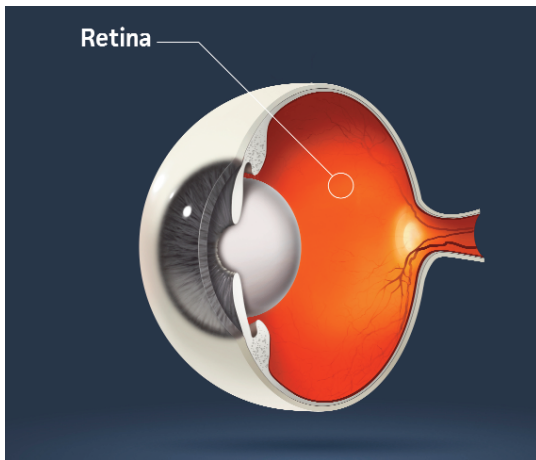
Of the approximate four million infants born in the U.S. every year, about 28,000 weigh 2¾ pounds or less. About 14,000-16,000 of those infants have some degree of ROP.⁸ Of those infants whose ROP progress beyond the mild type, 85% respond to surgical treatment.⁹ An average of two out of every serious 100 ROP patients will experience permanent vision loss.¹⁰ Poor outcomes can occur with even the very best of care.

THE DISEASE PROCESS

The vasculature of the retina begins to develop three months post-conception and is complete at the end of a normal gestation period. In normal development, these blood vessels form at the optic nerve in the posterior of the eye and then grow gradually to the edges of the developing retina where they will deliver nutrients and oxygen. In the last 12 weeks of gestation, the eyes develop rapidly.

When infants are born extremely premature, normal eye development can be disrupted. The blood vessels supplying the retina may cease growing or grow abnormally from the retina into the usually clear gel that fills the posterior portion of the eye. The retinal periphery may then send out signals for nourishment, resulting in the development of abnormal blood vessels, which are fragile and can develop leaks, bleeding into the eye. Scar tissue may form and pull the retina loose from the eye's inner surface. This retinal detachment is the primary cause of visual impairment and blindness for infants with ROP.^{11 12}

There still are significant gaps in modern medicine's understanding of the development of ROP. Current knowledge of causative factors includes, beyond prematurity and low birth weight, supplemental oxygen administration, and more recent studies show a possible link to a genetic component.¹³



DIAGNOSIS AND TREATMENT

Until the 1980s, no treatment for ROP existed. Then came cryotherapy, an ophthalmologic surgical procedure. Surgical intervention will often stop the abnormal growth of blood vessels and significantly reduce the progression of ROP.¹⁴ Treatment is dependent on timely diagnosis based on retinal examinations using binocular indirect ophthalmoscopy. The window in which treatment of ROP will work can be narrow – a matter of weeks.

The eye examination is performed by a pediatric ophthalmologist in a Level III neonatal intensive care unit (NICU). The preferred method of treatment has shifted from cryotherapy to laser therapy, but both types of surgery destroy the periphery of the retina through ablation, which retards or reverses the abnormal growth of the vasculature that, untreated, can cause severe or total loss of vision. Unfortunately, the procedures permanently reduce peripheral vision – and they are not always successful. Even with flawless care, some patients lose their vision.¹⁵

In 2009, ROP screening guidelines are based on those published in the journal *Pediatrics* in 2006 and promulgated jointly as a policy statement by the Section on Ophthalmology of the American Academy of Pediatrics, the American Academy of Ophthalmology and the American Association for Pediatric Ophthalmology and Strabismus.

These guidelines recommend screening eye examinations for: “Infants with a birth weight less than 1500 grams or gestational age of 30 weeks or less (as defined by the attending neonatologist) and selected infants with a birth weight between 1500-2000 grams or gestational age of more than 30 weeks with an unstable clinical course, including those requiring cardiorespiratory support and who are believed by their attending pediatrician or neonatologist to be at high risk should have retinal screening examinations using binocular indirect ophthalmoscopy to detect ROP.”¹⁶

Clinicians use other criteria as well in evaluating infants at risk. These include the location of ROP within the retina, the stage of the disease and the observed presence of vascular tortuosity (called plus disease).¹⁷ Dr. James D. Reynolds, Children’s Hospital Buffalo, a leading ROP expert, says, “Plus disease is probably the single most important retinal finding in the prognosis of this disease and is now the essential finding influencing treatment decisions. Hence the single most critical determining factor in ROP is an examiner judgment call, with all the inherent problems associated with that.”¹⁸

Dr. Reynolds correctly points out that these statements are guidelines and, as such, do not necessarily constitute a deviation from the standard of care, as long as what was done at the time was medically reasonable under the circumstances.

Telemedical imaging holds promise for improved care and treatment of ROP but continues to be studied for efficacy. At present, indirect ophthalmoscopy performed at the patient’s NICU bedside is the preferred approach to diagnosis.¹⁹

Thus treatment of ROP involves careful monitoring of oxygen saturation levels, peripheral retinal ablation by either cryosurgery or laser surgery, and surgery for the repair of retinal detachment, although outcomes for retinal surgery for detachment are poor.²⁰ Research is still under way to optimize therapy for ROP, as current treatments have limitations and patients are invariably left with long-term effects, ranging from damaged peripheral vision to blindness.^{21 22}

ROP CLINICAL MANAGEMENT: CHALLENGES

The paramount issue for clinically managing ROP is timely identification of the disease and early treatment. Delays in either identification or treatment can be devastating and give rise to litigation. The number of infants requiring screening examinations has increased significantly with more premature births and an expansion of the gestational-age criteria in the 2006 policy statement.

The 2006 statement discusses the coordination and communication that must occur in each NICU between the neonatology and ophthalmology services, and between the attending primary physicians, especially if the infant is transferred from a Level III NICU to a community hospital with either a Level I or II nursery.²³

If the infant is discharged to the parents, the doctor (or others) must communicate the critical time window for follow-up eye examinations and the potential for severe vision loss, including blindness, should those appointments not be kept.

Timely ROP screening and follow-up care can be a challenge for many reasons:

- Patients are discharged prior to the initial examination.
- Patients are discharged prior to the follow-up date.
- Patients are too ill for the initial examination.
- Patients are transferred to another facility.
- Socioeconomic factors may inhibit and delay the caregivers' return for follow-up visits.²⁴



ROP LITIGATION

The history of ROP litigation tracks the evolution of the pediatric community's understanding of the disease. The advent of the neonatal intensive care unit and administration of supplemental oxygen to premature infants treated in isolettes set the stage for the first wave of litigation. Until the 1980s, the major cause of ROP (then termed retrolental fibroplasia or RLF) was thought to be exposure of premature infants to high oxygen levels (hyperoxia). The chief allegation in these cases was negligent administration of inappropriately high levels of supplemental oxygen for prolonged periods of time or some variation thereof, such as failure to monitor oxygen levels by obtaining timely readings of blood gasses.²⁶

In the 1980s, technology was developed to continuously monitor oxygen levels in the blood through the use of intravascular and transcutaneous electrodes.²⁷ ROP was thought to be controllable, if not preventable. But the increased survivability of very low birth-weight infants, due to other significant clinical developments, put more infants at greater risk of developing ROP. While prolonged exposure to high levels of oxygen remains a risk factor, prematurity alone is a primary risk factor, particularly when measured by very low birth weight and gestational age at birth. The incidence of ROP in the U.S. is not decreasing. It is a worldwide problem occurring anywhere the health care delivery system allows sophisticated treatment of low birth-weight premature neonates.

With the increased ability to assess and treat the eyes of these infants, the focus of ROP litigation has changed since the 1980s. The chief risk management issue now is making sure patients do not fall through the cracks and either fail to receive a timely initial eye examination or appropriate follow-up, particularly after discharge from the NICU to the parents or to another facility. Improper administration of oxygen is no longer likely to be an allegation in litigation.

In 2007, Dr. Jame Reynolds reviewed 13 closed malpractice claims from 1999 to 2006 in a diverse geographic distribution – cases in which he functioned as a paid consultant or cases he found in the literature. (See tables on the following pages.) According to Dr. Reynolds, recent cases chiefly follow two recurring fact patterns:

- A failure on the part of the neonatologist(s) and team in the NICU to appropriately refer a patient for an ophthalmology consult and screening eye examination
- A failure by the ophthalmologist to properly follow and diagnose the patient, often due to clerical and/or administrative functions or lack thereof²⁸

Reynolds also found that those 13 cases frequently involved other issues, such as failure to educate the parents on the necessity of return visits, failure to supervise residents involved in care and consistency of documentation. Ten of the 13 cases reviewed were settled. Two that went to verdict resulted in awards (\$15 million in 2001 in Texas and \$6 million in New Jersey in 2004).

BASELINE CHARACTERISTICS OF 13 RETINOPATHY OF PREMATURITY (ROP) MALPRACTICE CASES²⁹

CASE	STATE	DISPOSITION	AWARD		
			PARTY	AMOUNT	DATE
GA 26 wk BW 890 g	Arizona	Settlement/Arbitration following verdict	Obstetrician Pediatrician Hospital/Resident	\$150,000	1999
				\$1.2 million	2000
GA 23 wk BE 535 g	Florida	Settlement	Hospital	\$1 million	1999
GA 27 wk BW 848 g	Connecticut	Settlement		Plaintiff favor	1999
GA 25 wk BW 640 g	North Carolina	Settlement after trial	Pediatrician Hospital	\$1.1 million	2000
				\$2.4 million	
GA 29 wk BW 1170 & 1406 g	Texas	Verdict Appeal	All Ophthalmologist	\$15 million	2001
				Reversed	2004
GA 27 wk BW 950 g	Illinois	Settlement	Neonatologist	Defendant favor	2001
GA 30 wk BW 1530 g	North Carolina	Settlement	Ophthalmologist	Defendant favor	2001
GA 27 w BW 540 g	Virginia	Settlement after trial	Ophthalmologist Hospital/Neonatologist	Nonsuited Plaintiff favor	2002
GA 25 wk BW 790 g	British Columbia	Settlement	Ophthalmologist	Defendant favor	2002
GA 26 wk BW 921 g	New Jersey	Dismissed		None	2002
GA 25 wk BW 553 g	Missouri	Settlement		Confidential	2004
GA 29 wk BW 1530 g	New Jersey	Verdict	Pediatrician/ Neonatologist Ophthalmologist	\$6.0 million	2004
				\$0	2004
GA 24 wk BW 787 g	Hawaii	Settlement	Confidential		2006

*BW = birth weight, GA = gestational age.

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In this series, 10 of 13 cases were settled. Of those, seven were settled prior to trial or verdict, and three were settled after the verdict was rendered, but before the award amount was determined. Ten of the 13 involved a settlement. One was dismissed. One went to verdict and a large court-determined plaintiff award was partially vacated on appeal by one defendant. One went to verdict and a large court-determined plaintiff award in that case is still subject to appeal.

Not every defendant was assigned equal responsibility. Even in cases that result in a large award, individual defendants may be found to have zero or very little responsibility.

Each of the 13 cases involves a complex series of events, in medically complicated patients dealing with an extremely complex disease. However, the actual medical facts in the cases are relatively straightforward. The interpretation of those facts and the nondocumented testamentary facts usually decide such malpractice cases.

SUMMARY OF MEDICAL CARE ISSUES IN RETINOPATHY OF PREMATURITY IN 13 CASES²⁵

ISSUE	NO. OF CASES
Failure to refer/missed window of opportunity – inpatient vs. outpatient vs. transfer (neonatologist/pediatrician)	8
Failure to educate parents (neonatologist/pediatrician)	3
Failure to oversee (hospital)	7
Failure to follow up (ophthalmologist)	6
Failure to supervise (ophthalmologist/resident ophthalmologist)	2
Negligent examination/diagnosis (ophthalmologist)	9
Negligent treatment (ophthalmologist)	0
Rare but expected occurrence (ophthalmologist)	2
Zone III (ophthalmologist)	4
Issue of harm (all)	3

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A study published by Dr. Shelly Day, et al. in June 2009, reviewed 12 closed ROP malpractice claims filed from 1987 through 2003 involving ophthalmologists insured by Ophthalmic Mutual Insurance Company (OMIC). Nine of the 12 cases involved litigation. Eight involved the failure of appropriate transfer of the patient’s care between the NICU and the subsequent treating ophthalmologist in an outpatient setting, also an issue in Reynolds’s case reviews. The authors correctly assert that this is a “...weakness in the chain of care of premature infants” due to the complex interaction required between the neonatologist, ophthalmologist, nursing and other hospital staff, pediatrician and the patient’s family.³⁰

Another common issue identified in the OMIC claim study was “an inappropriate length of time between follow-up examinations.” Responsibility for appropriately timed follow-up examinations and appointments falls upon the ophthalmologist.³¹

Two trial verdicts in the last three years have potentially ratcheted up the economic valuation of ROP cases and focused more attention on ROP risk than ever before. The first one was the Lee case from suburban Philadelphia in November 2006. The chief allegation was a failure to advise the parents of the need for timely follow-up examinations, which resulted in the child’s complete blindness.

The jury award was \$20 million.³² This case sent shock waves through the pediatric community, especially pediatric hospitals, hospitals with Level III NICUs, pediatric ophthalmologists and retinal specialists.

The second case involved twins in Ft. Myers, FL in April of 2008. The chief allegation in this case was the ophthalmologist’s failure to appropriately screen and diagnose ROP. The defense asserted comparative negligence on the part of the mother for failing to bring the twins for their appointments. The jury awarded \$38 million after a 14-day trial.³³

Any malpractice case involving an injured child is difficult to defend given the sympathies evoked and the expense of life-care plans. These two cases have made current and future ROP litigation even more potentially volatile.

ROP LITIGATION: IMPACT

ROP litigation has occurred with enough frequency and highly publicized severity to adversely affect the health care delivery system in the U.S. One author reviewed the “nearly perfect storm of converging negative influences” confronting clinicians involved in treating ROP:

- More infants to be examined and more frequent eye exams
- Too few ophthalmology residents choosing pediatrics as a subspecialty
- Regions/cities underserved due to lack of ROP experts
- Inadequate reimbursement for ROP eye exams
- Difficulty in tracking patients after discharge
- Risk of litigation³⁴

A survey by the American Academy of Ophthalmologists in 2006 found that just 54% of retinal specialists and pediatric ophthalmologists were managing ROP cases and that 20% had planned to cease ROP treatments because of concerns over malpractice exposure and inadequate reimbursement.³⁵ Malpractice liability was cited by 67% of the ophthalmologists who had ceased managing ROP cases.³⁶

ROP: RISK MANAGEMENT

Perhaps the best publication on risk management for ROP is *Retinopathy of Prematurity: Creating a Safety Net*, written by Anne Menke, RN, PhD, the Risk Manager for OMIC, and available on the OMIC website. This document provides protocols for promoting patient safety and risk management for ROP care in the hospital and for outpatient ROP care. The article reviews such important issues as timeliness of the initial eye exam, developing a hospital ROP tracking system, providing caregivers with education, and discharge/transfer planning.³⁷ It also provides sample documents for informed consent and caregiver education. The article by Day, Menke and Abbot previously cited also promotes patient safety with seven brief recommendations for helping to ensure patients receive appropriate ROP screening and follow-up.³⁸

The development of a formalized tracking system with responsibilities assigned and agreed upon by the health care team is an important component of patient safety and risk management, as is documentation of discharge instructions and consent to treatment. Many hospitals have designated an ROP coordinator, often a nurse, to handle this documentation responsibility, although this is only one approach to addressing the potential for ROP patients to fall through the cracks.³⁹

CONCLUSION

Timely screening, diagnosis and treatment of premature infants with ROP are critical factors in litigation involving ROP. Recent cases have raised the stakes for these cases and heightened the importance of creating coordinated care plans understood by all staff treating patients with ROP. Fortunately, the medical community is developing a growing body of literature on ROP malpractice claim issues, ROP patient safety, and managing the risk of ROP liability.

FOOTNOTES

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- ²³ AAP Policy Statement, 2006, p. 575.
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