

## EVIDENCE-BASED MEDICINE REGARDING THE PREVENTION OF RETINAL DETACHMENT\*

BY C. P. Wilkinson, MD

### ABSTRACT

*Purpose:* To assess the quality of information in the literature regarding the prevention of retinal detachment in an effort to establish appropriate practice guidelines.

*Methods:* A panel of vitreoretinal experts performed a literature review of all publications in the English language for articles about prevention of retinal detachment. These articles were then used to prepare recommendations for patient care in an American Academy of Ophthalmology "Preferred Practice Pattern" (PPP). Each recommendation was rated according to its importance in the care process and the strength of evidence supporting the given recommendation.

*Results:* Most recommendations were given a rating of "A" (most important to patient care). Only a single publication was graded as Level I (providing strong evidence in support of a recommendation), and this was not a prospective trial. Of the few publications rated as Level II (substantial evidence), most were studies documenting a lack of treatment benefit. Because of an absence of Level I and Level II studies in the literature, Level III (consensus of expert opinion) was the basis for most recommendations in the PPP.

*Conclusion:* The current literature regarding prevention of retinal detachment does not provide sufficient information to strongly support prophylactic treatment of lesions other than symptomatic flap tears. Prospective randomized trials of prophylactic therapy are indicated. Eyes highly predisposed to retinal detachment should be considered for such studies.

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### INTRODUCTION

Evidence-based medicine represents an effort to use the best current scientific evidence in formulating management decisions regarding the care of individual patients. The development of practice guidelines such as the Preferred Practice Patterns (PPPs) of the American Academy of Ophthalmology (AAO) is also dependent on the identification of optimal research results, because the quality of such publications is a function of the strength of the evidence supporting the recommendations contained in the documents.

O'Day and associates<sup>1</sup> described the lack of meaningful evidence in ophthalmology literature searches on the subject of cataract. However, a large number of prospective multicenter randomized trials of posterior segment disorders, including diabetic retinopathy, age-related macular degeneration, and retinal venous occlusive disease, have been published, and there is evidence that practice guidelines based on these research data have been implemented in the ophthalmologic community.<sup>2</sup>

The AAO mandates periodic review and update of the topics discussed in its PPPs. The most recently modified versions contain both a description of the newest evidence used to prepare recommendations and a specific rating of each recommendation.<sup>3</sup> During the latest revision of the PPP devoted to prevention of retinal detachment, the quality and weaknesses of the current literature became evident, and these deficiencies are the subject of this report.

### METHODS

With the dedicated assistance of the AAO's PPP Retina Panel (Table I), the author conducted a thorough literature search of articles in the

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**TABLE I: MEMBERS OF THE AMERICAN ACADEMY OF OPHTHALMOLOGY'S PREFERRED PRACTICE PATTERN RETINA PANEL**

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C. P. Wilkinson, MD, Chair  
 Michael A. Bloome, MD  
 Emily Y. Chew, MD  
 Louis A. Lobes Jr, MD  
 David W. Parke II, MD  
 Dennis Robertson, MD  
 Marco Zarbin, MD, PhD  
 Paul P. Lee, MD, JD, Methodologist, Consultant  
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 Flora Lum, MD, AAO staff

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English language that were devoted to the topics of posterior vitreous detachment, lattice degeneration, retinal breaks, and other conditions associated with rhegmatogenous retinal detachment. These publications were reviewed by the Retina Panel and used in preparation of the recommendations contained in the updated PPP. In addition, each recommendation was rated in two ways.

The first rating concerned the importance of the specific recommendation to the care process. This “importance to the care process” rating represented care that the Panel believed would improve quality in a meaningful way. The ratings were divided into three levels:<sup>3</sup>

- Level A, defined as most important
- Level B, defined as moderately important
- Level C, defined as relevant but not critical

The second rating concerned the strength of evidence in the available literature that was referenced and used to support each recommendation. The ratings of “strength of evidence” were also divided into three levels:<sup>3</sup>

- Level I, defined as data that provided strong evidence in support of the recommendation. The design of the study addressed the issue in question, and the study was performed in the population of interest and executed in a manner that ensured production of accurate and reliable data, using appropriate statistical methods.
- Level II, defined as data that provided substantial evidence in support of the recommendation. The study had selected attributes of Level I support but lacked one or more of the components of Level I.
- Level III, defined as a consensus of expert opinion in the absence of evidence that met Levels I and II.

Ratings of importance to care and strength of evidence were provided after each recommendation. For instance, a rating of “(A:II)” indicated a recommendation with high importance to clinical care (A), supported by meaningful published evidence (II) but not by a randomized controlled trial or a retrospective study with a highly significant statistical outcome.

## **RESULTS**

The vast majority of recommendations were considered to be Level A, most important to the quality of patient care. However, the strength of the evidence used to support the recommendations was surprisingly weak. No prospective randomized clinical trials on the prevention of retinal detach-

ment have been published. Of the 25 recommendations regarding treatment that were published in the new PPP,<sup>3</sup> a rating of "I" was applied to a single recommendation for therapy, to treat symptomatic flap ("horse-shoe") tears. This rating was based on a number of primarily retrospective studies demonstrating that untreated flap tears frequently progress to clinical retinal detachment, whereas treatment of similar cases is usually effective in preventing this complication (Table II).

TABLE II: OUTCOMES ASSOCIATED WITH SYMPTOMATIC FLAP TEARS °

GROUP	SENIOR AUTHOR	NO. OF CASES	RETINAL DETACHMENT INCIDENCE (%)
Treated eyes	Shea	48	4.2
	Robertson	88	7.8
	Verdaguer	74	5.4
	Pollack	74	1.4
Untreated eyes	Colyear	20	55
	Shea	21	48

°Complete references cited in reference 4.

A Level II rating ("substantial evidence") was applied to 8 recommendations regarding therapy (Table III). These included a recommendation of "rarely treat" in 4 instances, "don't treat" in 3 situations, and "sometimes treat" in a single setting.

Neither "strong" (Level I) nor "substantial" (Level II) evidence was available to support 16 of the 25 recommendations. Therefore, these 16 were rated as Level III, "consensus of opinion" (Table III). These included a recommendation to "rarely treat" in 6 situations, "sometimes treat" in 5 instances, and "almost always treat" in 5 additional settings

## DISCUSSION

Current management of many posterior segment disorders, including diabetic retinopathy, age-related macular degeneration, and venous occlusive disease, is based on results of prospective randomized collaborative trials. However, our review of the ophthalmologic literature devoted to prevention of retinal detachment revealed that optimal trials regarding prophylactic treatment are unavailable. Prospective randomized trials of therapy to prevent retinal detachment have not been performed. Our search for the best available evidence indicated that only a single recommendation—to promptly treat symptomatic flap tears—was supported with data of

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**TABLE III: RATING OF RECOMMENDATIONS FOR THERAPY USED FOR THE AMERICAN ACADEMY OF OPHTHALMOLOGY'S PREFERRED PRACTICE PATTERN**

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**Level II**

## Rarely Rx

- Asymptomatic atrophic holes
- Asymptomatic lattice degeneration in aphakic/pseudophakic eyes
- Symptomatic atrophic holes
- Symptomatic lattice degeneration with and without holes

## No Rx

- Asymptomatic operculated breaks
- Asymptomatic lattice degeneration with or without holes in (1) phakic and (2) myopic eyes

## Sometimes Rx

- Lattice degeneration with and without holes in fellow eyes (of patients with a history of retinal detachment in the first eye)

**Level III**

## Rarely Rx

- Asymptomatic operculated breaks in (1) myopic, (2) fellow, and (3) aphakic/pseudophakic eyes
- Symptomatic atrophic breaks in (1) myopic, (2) fellow, and (3) aphakic/pseudophakic eyes

## Sometimes Rx

- Asymptomatic flap tears in (1) phakic, (2) myopic, (3) fellow, and (4) aphakic/pseudophakic eyes
- Symptomatic operculated breaks

## Almost always Rx

- Asymptomatic dialysis in (1) phakic, (2) myopic, (3) fellow, (4) aphakic/pseudophakic eyes
  - Symptomatic eyes with dialysis
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Adapted from American Academy of Ophthalmology.<sup>3</sup>

significant strength. Seven of the 8 recommendations that were based on Level II data were for no prophylactic therapy or for its “rare” use. Only one Level II recommendation was worded somewhat more enthusiastically, to “sometimes” treat lattice degeneration, with or without retinal holes, in fellow eyes of patients with a history of detachment in the first eye.

All of the remaining 16 recommendations were based on a rating of Level III, “consensus of expert opinion.” Although these included a recommendation to “almost always treat” in 5 of 16 instances and to “sometimes treat” in 5 additional situations, the genuine value of this level of support is both lower than Levels I and II and questionable in many instances. An analysis of selected examples of a “consensus of expert opinion” regarding the management of specific vitreoretinal pathology reveals

major contradictions with the evidence contained in the best available literature regarding the lesions in question.

For instance, H. M. Freeman (written communication, 1998) recently conducted a poll of 138 members of vitreoretinal subspecialty societies. These individuals were asked if they would treat a number of specific vitreoretinal lesions prior to cataract surgery. An analysis of the responses demonstrates remarkable contrast with evidence in the literature that was used in the PPP. Four percent of poll responders recommended treatment of lattice degeneration without holes, but 17% recommended therapy for lattice degeneration with holes, in spite of evidence that the course of lattice degeneration is usually not influenced by the presence of holes within lattice lesions.<sup>5</sup> Moreover, 51% recommended treatment of lattice in eyes with 8 diopters (D) or more of myopia, and 83% recommended therapy if the other eye had a previous retinal detachment. These recommendations from the individuals polled contradict the best published evidence, which indicates that the value of treatment of fellow eyes with lat-

TABLE IV: OUTCOMES IN FELLOW EYE

FELLOW EYE	NO. OF EYES	% DETACHMENT	COMMENTS
Phakic: <sup>6</sup>			
• No. Rx	151	5.9	Treatment was of no value in eyes with > 6 D of myopia or > 6 clock hours of lattice
• All lesions Rx	164	1.8	
• No Rx, 7-yr follow-up		5.1	
• Full Rx, 7-yr follow-up		1.8	
Aphakic: <sup>7</sup>			New tear location*:
• Treated	24	8.3	• 100% normal
• Untreated	100	19.0	• 89.5% normal, 10.5% abnormal

\*Successful treatment of a visible vitreoretinal lesion would have prevented only 2 of 21 retinal detachments that occurred in this series.

tice degeneration is modest at best (Table IV) and that treatment is of no value in eyes with more than 6 D of myopia or with more than 6 clock-hours of lattice degeneration.<sup>6</sup>

Another frequently cited study<sup>7</sup> indicated that treatment of peripheral vitreoretinal lesions, prior to or following cataract surgery, was valuable in fellow eyes of patients with a history of retinal detachment in their first eye. Later, retinal detachment occurred in 19% of 100 untreated eyes but in only 8.3% of 24 treated cases (Table IV). However, further analysis of

these data reveals that the breaks responsible for later detachment occurred in areas of the retina previously considered normal in 89% of the untreated eyes and in all treated cases, so the treatment of all visible lesions in all eyes in the series would have prevented only 2 of 21 detachments.

Perhaps the most obvious example of the paucity of meaningful evidence supporting treatment to prevent retinal detachment is data obtained in a prospective trial<sup>8</sup> of aphakic eyes in patients who had a history of retinal detachment surgery in their other eye. Eighty-three such cases were followed. Forty-three of these had evidence of a posterior vitreous detachment (PVD) at the time of entry into the study, and 40 did not. Only a single patient in the former group (2.3%) developed a subsequent retinal detachment. However, PVDs developed in 11 eyes that did not initially exhibit this change, and retinal detachments developed in 8 of these, representing 20% of the original 40 eyes without PVD. Despite the dramatic importance of the state of the vitreous gel on the likelihood of future retinal detachment, the PVD variable has not been included in any other published study, known to the Panel, regarding preventative therapy!

Myopia, lattice degeneration, cataract surgery, and a history of retinal detachment in a fellow eye are clearly risk factors for retinal detachment.<sup>3,5</sup> However, demonstration that vitreoretinal lesions increase risk does not justify the treatment of these disorders in the absence of scientific evidence that the therapy genuinely lowers the rate of subsequent retinal detachment.<sup>4,5</sup>

As evidence-based medicine becomes increasingly important as a method of improving many aspects of medical care, better studies of therapy to prevent retinal detachment are clearly necessary. Prospective randomized trials of treatment for eyes with a relatively high risk of later detachment should offer the best opportunity to provide outcome data that are statistically meaningful. Such cases might include highly myopic fellow eyes with lattice degeneration and no PVD, which are also pseudophakic or scheduled for cataract surgery. Such a prospective trial should include an appropriate number of cases followed over a lengthy period to ensure that the questions regarding outcomes of therapy versus no therapy are answered in a satisfactory statistical fashion.

#### ACKNOWLEDGMENTS

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## DISCUSSION

DR WILLIAM E. BENSON. I would like to congratulate Dr Wilkinson on his excellent study. He properly focuses on the fact that much of what we do or do not do is based on inadequate scientific evidence. I can assure you that this will change, because health care is entering a new era in the United States. Patients and payers are demanding not only quality medicine but also cost-effectiveness.

Evidence-based medicine is now on the cutting edge of health care. Its goal is to help us provide high-quality, cost-effective care by identifying practices and procedures based on the highest-quality scientific data. The best evidence, of course, is a prospective, randomized multicenter clinical trial such as the Diabetic Retinopathy Study. Of lesser value, in descending order, are studies that compare treatment results with historical controls, interventional case series, and interventional case reports. Dr Wilkinson's study and the American Academy of Ophthalmology's "Preferred Practice Patterns" also rely on consensus of expert opinion, but while this is valuable, historical evidence shows us that time often proves experts to be wrong. In 1960, Professor Gerd Meyer-Schwickerath, one of the greatest retinal surgeons of all time, wrote that "light coagulation was developed for the treatment of macular holes, and these remain among the simplest and most successful indications for this form of treatment."<sup>1</sup> The days of anecdotal medicine are ending. Insurers, including the Health Care Finance Administration, increasingly indicate that they will not pay for treatments based on clinical impression or treatments proved

to be ineffective by well-designed clinical trials.

Dr Wilkinson's excellent study concludes that when we look at all the retinal lesions and breaks that have been treated to prevent retinal detachment, only for acute flap tears is there sufficient scientific data to support prophylactic treatment. A purist could even dispute this recommendation, since it is based on the comparison of interventional case series with historical controls. No prospective trial has ever been done. The problem is that clinicians continue to treat lesions considerably less likely to lead to retinal detachment. I have to confess that while I agree with Dr Wilkinson intellectually, I sometimes lack the courage of my convictions. I would like to open the discussion by asking what he would recommend to me if I presented to his office with a one-day history of flashes and floaters, a superior operculated tear, and a moderate vitreous hemorrhage.

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DR H. MACKENZIE FREEMAN. I would like to comment on one special situation: the fellow eye in patients with a giant retinal tear. This was the subject of my thesis. In following over 300 eyes, I found a group of high-risk cases. These were patients who had high myopia, condensation of the vitreous base, and increasing white with pressure. Ninety-one percent of fellow eyes in that group developed a giant retinal tear. Many of these cases were monocular, so I did prophylactic scleral buckling surgery; the incidence of giant retinal tears in those eyes, which we have followed an additional 20 years, is about 8% to 10%. Therefore, I believe that in these special cases, there is an indication for prophylactic scleral buckling surgery, and it is documented in my AOS thesis.

DR C. P. WILKINSON. Thanks to Dr Benson for his remarks and for his interesting question.

Thanks also to Dr Freeman for reminding us of his remarkably large series of non-traumatic giant tear cases, in which treated and untreated fellow eyes were compared. These type of cases were not discussed in the AAO PPP because they are relatively unusual. Dr Freeman initially demonstrated a tremendous risk of giant retinal tears and retinal detachments in myopic eyes of patients with a history of myopia and non-traumatic giant retinal tear in their first eye, and this high incidence of retinal detachment was reduced significantly by prophylactic scleral buckling. However, it is important to recognize that progressive changes in the

region of the vitreous base were usually observed prior to the development of a retinal tear. Many vitreoretinal surgeons currently recommend preventative scleral buckling in fellow eyes which exhibit such changes.

Dr Benson is correct in predicting that all of us will be required to provide increasing evidence of a proven value for many of our treatment recommendations in the future. It is important that we take a more evidence based approach to many areas in ophthalmology in which genuine scientific evidence is lacking. My finding of contradictions between a consensus of opinion of genuine experts and the best data available regarding treatment of selected vitreoretinal lesions is a clear indication that better information, in the form of prospective randomized trials, is needed.

Dr Benson asked how I would manage a patient with a symptomatic vitreous hemorrhage and an operculated retinal tear. My short answer would be that I would not treat such a retinal break if I were certain that there was no persistent vitreoretinal traction in the region of the tear. It might surprise some of you to know that a case in which such a tear progressed to clinical retinal detachment has never been reported. Davis and Pishell/Colyear were cited in my manuscript for describing progressive retinal detachments due to operculated tears associated with persistent vitreoretinal traction upon a vessel near the tear. But these are cases which behave as flap tears because of persistent vitreoretinal traction near the break, and they are unusual. If vitreous hemorrhage prohibited an optimal view or if I were not certain that all vitreoretinal traction had been eliminated by the PVD in the region of the tear, I would treat it, because such therapy is unassociated with genuine risk.

Another "real-life dilemma" occurs when such a patient is referred by a physician who has recommended therapy and instructed the patient that prophylactic treatment will be performed. In this situation, I remain sufficiently hypocritical to usually proceed with treatment, which indeed remains a standard of care in our community. But I would encourage you in the audience to photograph those operculated tears unassociated with persistent vitreoretinal adhesions, because progression to detachment has not been reported, and Dr Minkler would be most happy to receive a publication which disproves my thesis.