OPHTHALMOLOGIST PERCEPTIONS REGARDING TREATMENT OF MODERATE TO SEVERE DRY EYE: RESULTS OF A PHYSICIAN SURVEY

By Penny A. Asbell MD MBA* and Scott Spiegel PhD

ABSTRACT

Purpose: To understand ophthalmologists' current perceptions and treatment of patients with moderate to severe dry eye syndrome (DED).

Methods: An online survey was distributed to 7,882 ophthalmologists, including 51 corneal specialists, throughout the United States from October 9 to 21, 2008. The response rate was 3.1% (n = 245), typical for this type of survey. Those who treated 4 or more patients with moderate to severe DED per month (235 of 245 [96%]) were asked to complete the survey.

Results: Ninety-four percent of respondents agreed that more treatment options are needed for moderate to severe DED. Corneal specialists were more likely to strongly agree (63%) than general ophthalmologists (54%). Only 33% overall felt that current therapies were extremely or very effective for moderate DED, and only 5% for severe disease. Ninety-two percent agreed that multiple therapeutic agents are needed to manage moderate to severe DED. The respondents reported prescribing, recommending, or suggesting a mean of 3.2 different treatment approaches over the course of a year for patients with moderate DED and 4.9 for patients with severe DED. The most highly ranked goals in treatment of moderate to severe DED were maintaining and protecting the ocular surface (ranked 1 or 2 by 74%) and lubricating and hydrating the ocular surface (ranked 1 or 2 by 67%). Corneal specialists ranked maintaining and protecting the ocular surface even higher (ranked 1 or 2 by 82%).

Conclusions: Results reflected the difficulty of treating more serious moderate to severe cases, the importance of using multiple treatment approaches, the limitations of current treatment options, and the need for additional treatment options.

Trans Am Ophthalmol Soc 2009;107:205-213

INTRODUCTION

Dry eye syndrome (DED) is characterized by one or more of the following symptoms: burning, itching, foreign body sensation, soreness, dryness, photophobia, redness, and reduced visual acuity.^{1,2} The tear film instability of DED, which is accompanied by increased osmolarity of the tear film, causes inflammation and structural damage to the ocular surface.¹

Dry eye syndrome is a common clinical problem affecting approximately 1 in 3 patients who seek treatment from an ophthalmologist.² Approximately 5 million Americans aged 50 years and older have DED, and twofold more women than men. In our aging population, the number of people with DED can be expected to increase dramatically.³

Although DED affects all aspects of a patient's work, leisure, and social life, it poses a challenge to the clinician who must diagnose and treat this disorder. There is a lack of correlation between patients' symptoms and the results of clinical tests as well as inter- and intra-person variability in the disease process and its symptoms. Repeatable, reliable tests are unavailable,³ and there is variability in responses to questions about the physical sensations in the eyes, along with observer bias in recording slit-lamp findings.³ This has led to a difficult dilemma: some patients may present with ocular damage but no or few symptoms of DED.²

A panel of questions was presented to practicing ophthalmologists throughout the United States to determine their perceptions of moderate to severe DED and how it is treated, and to identify areas of unmet therapeutic need for this disease.

METHODS

Survey questions (see Appendix) assessing participant demographics, perceptions of moderate to severe DED, DED treatment goals, DED therapeutic characteristics, measures of therapeutic success, and potential treatment gaps in DED were sent to 7,882 of the approximately 23,000 practicing ophthalmologists in the United States. Target ophthalmologists, who specialize in corneal/external eye disease, were identified by combining a pool of prespecified e-mail addresses with a list of subscribers to *Ophthalmology Times*. Prospective participants were sent an e-mail with a Web link to the online survey. To encourage participation in the survey, respondents were enrolled in a drawing to win a single prize of moderate value. No product was mentioned in either the invitation or the survey. Responses were collected from October 9 to 21, 2008, and were summarized in frequency tables organized by query. No comparative analyses were anticipated or utilized in this survey. An institutional review board waiver was provided to conduct this survey.

RESULTS

RESPONDENT DEMOGRAPHICS

Of 7,882 targeted ophthalmologists, 245 (3.1%) submitted completed surveys. Of the participants, the majority (73.9%; n=181) were male, 21.2% (n=52) were female, and 4.9% (n=12) did not specify their gender. Respondents represented all regions of the United States: the Northeast (25.3%; n=62), the Southwest (22.0%; n=54), the Southeast (20.0%; n=49), the Midwest (19.6%; n=48), the Northwest (2.0%; n=5), and other regions of the United States, including Puerto Rico (1.6%; n=4). Ten respondents (4.1%) were

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Bold type indicates AOS member.

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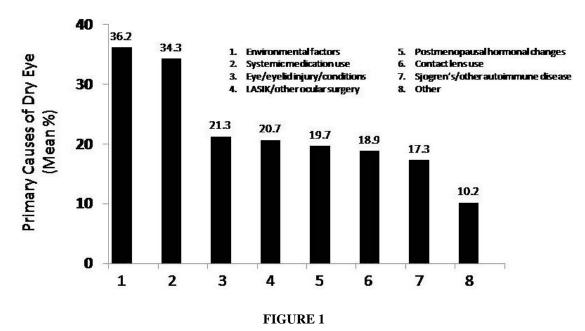
from outside the United States, and 13 (5.3%) did not specify their location.

Respondents spent an average of 17.4 years in practice. The majority of participants (66.1%; n = 154) had been in practice for more than 10 years. Most respondents indicated that they were comprehensive ophthalmologists (66.2%; n = 153), and 22.1% (n = 51) stated that they were corneal specialists. Twenty-seven (11.7%) indicated that they were involved in another specialty, and 5.7% (n = 14) did not provide a response to this query. On average, participants reported that they see 112.4 patients per week; of these, approximately 1 in 5 (n = 23.1) are patients with mild, moderate, or severe DED. Respondents who treat fewer than 4 moderate to severe DED patients per week (<4% of total respondents) were not included in the analysis of subsequent responses.

PERCEIVED CAUSES OF DRY EYE SYNDROME

Respondents were asked to indicate by percentage range the primary cause of DED among their patients with moderate to severe disease. Participants could select more than one category as a primary cause; results presented are not cumulative. Listed primary causes included Sjögren syndrome or other autoimmune disease, environmental conditions, postmenopausal hormonal changes, laser in situ keratomileusis (LASIK) or other ocular surgery, contact lens use, use of systemic medications, and eye/eyelid injury or conditions. Participants were permitted to write in another primary cause of DED if it was not included in the list provided. Respondents indicated that environmental factors and postmenopausal hormonal changes are the most common primary causes of moderate to severe DED in their patients, affecting an average of 36.2% and 34.3%, respectively (Figure 1). Participants indicated that use of systemic medications (21.3%), contact lens use (20.7%), eye/eyelid injury or conditions (19.7%), Sjögren syndrome or other autoimmune disease (18.9%), and LASIK or other ocular surgery (17.3%) were also primary causes of DED in their patients.

Survey participants were also asked to indicate if they believed inflammation is the underlying cause of DED, or whether it is merely a consequence of the disease. The majority of respondents (68.6%; n = 168) indicated that inflammation is the underlying cause of DED, whereas 26.1% (n = 64) felt that inflammation is a consequence of the disease. Thirteen participants (5.3%) did not provide an answer to this question.

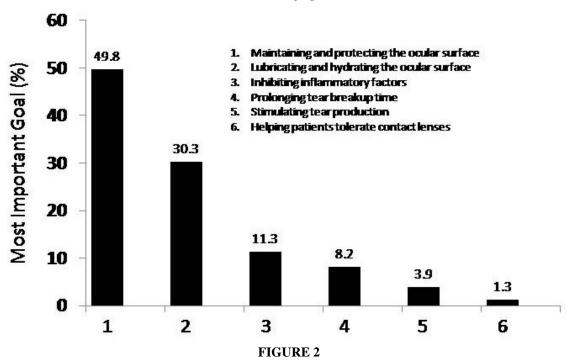


Primary causes of moderate to severe dry eye syndrome expressed as mean percentage of total responses. "Don't know" responses were excluded from mean calculations.

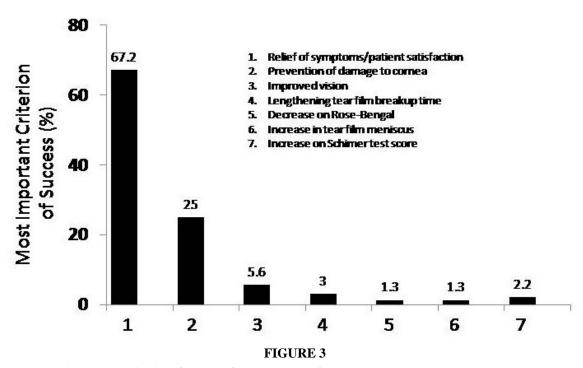
TREATMENT GOALS AND THERAPY OF MODERATE TO SEVERE DRY EYE SYNDROME

Participants were asked to rank, in order of overall importance, the goals of treatment for moderate to severe DED. On a scale of 1 (most important) to 6 (least important), respondents could rank among the following options: prolonging tear film breakup time, stimulating tear production, lubricating and hydrating the ocular surface, inhibiting inflammatory factors, helping patients tolerate contact lenses, and maintaining and protecting the ocular surface. As summarized in Figure 2, survey participants indicated that the most important goal of DED treatment is maintenance and protection of the ocular surface (mean score, 1.0), followed closely by lubrication and hydration of the ocular surface (mean score, 1.4).

Survey respondents were asked to rank determinants of successful treatment of moderate to severe DED on a scale of 1 (most important) to 7 (least important). Criteria for measuring successful treatment included lengthening of tear film breakup time, decrease in rose bengal, fluorescein, or lissamine green staining, increase of Schirmer test score, improved vision, relief of symptoms/patient satisfaction, increase in tear film meniscus, and prevention of damage to the cornea. As summarized in Figure 3, participants indicated that relief of symptoms/patient satisfaction (mean score, 1.0) was the most important determinant of successful treatment for moderate to severe DED, followed by prevention of damage to the cornea (mean score, 2.5).



Most important goal for the treatment of moderate to severe dry eye syndrome expressed as mean percentage of total responses.



Most important criteria of successful treatment of moderate to severe dry eye syndrome expressed as mean percentage of total responses

The survey also asked participants to estimate how many different treatment approaches they prescribe or recommend for mild, moderate, and severe DED over the course of 1 year. Respondents prescribe or recommend an average of 1.9 treatment approaches for mild DED, 3.2 approaches for moderate DED, and 4.9 approaches for severe DED. 23.4% of the participants were using four or more approaches to treat moderate dry eye, while 72.1% were using four or more approaches to treat severe dry eye. (Table 1).

TABLE 1. NUMBER OF ANNUAL DRY EYE SYNDROME PRESCRIPTIONS OR TREATMENT RECOMMENDATIONS PER PATIENT*									
DISEASE			NO. OF T	TREATME	NT APPR	OACHES			TOTAL
SEVERITY	0	1	2	3	4-5	6-7	8-10	11+	MEAN
Mild	0.4%	36.1%	47.4%	12.2%	3.0%	0.4%	0%	0.4%	1.9
Moderate	0.4%	0.9%	27.7%	47.6%	18.2%	4.8%	0.4%	0%	3.2
Severe	0.4%	0.9%	3.1%	23.6%	47.6%	14.8%	6.6%	3.1%	4.9

^{*}Based on survey question: On average, over the course of a year of treating a dry eye patient, approximately how many different treatment approaches do you prescribe, recommend, or suggest?

Participants were also asked to select which qualities of treatment options for DED they take into consideration when developing a treatment plan for a patient with moderate to severe DED. Respondents could select from a list including preservative-free, dosing frequency, length of time preserving the tear film, length of time to effectiveness, patient acceptance, ability to use with contact lenses, ability to provide continuous relief, ability for concomitant use with other medications, and ability to use long-term. The treatment characteristics participants most frequently selected as key considerations (summarized in Table 2) were the ability to provide continuous relief (84.2% of participants selected this answer) and patient acceptance (82.5% of participants chose this response).

TABLE 2. KEY CHARACTERISTICS OF THERAPIES FOR MODERATE TO SEVERE DRY EYE SYNDROME*						
QUALITY OF TREATMENT OPTION	N	% RESPONDENTS SELECTING ANSWER				
Ability to provide continuous relief	197	84.2				
Patient acceptance	193	82.5				
Ability to use long-term	173	73.9				
Dosing frequency	155	66.2				
Length of time preserving the tear film	155	66.2				
Length of time to effectiveness	148	63.2				
Preservative-free	126	53.8				
Ability to use with contact lenses	119	50.9				
Ability for concomitant use with other medications	102	43.6				
Other (please specify)	9	3.8				

^{*}Based on the survey question: When selecting products for moderate to severe dry eye patients, which of the following are key considerations? (Multiple responses allowed.)

AREAS OF CONCERN WHEN TREATING MODERATE TO SEVERE DRY EYE SYNDROME

The survey asked respondents to indicate how effective they feel current therapies for mild, moderate, and severe DED are, ranging from extremely effective to not effective at all. The majority of participants (79.9%; n = 187) indicated that current treatments for mild DED are extremely or very effective, whereas 32.5% (n = 76) ranked therapies for moderate DED in this category. Twelve (5.1%) of the respondents indicated that current treatments for severe DED are extremely or very effective, and 38.2% (n = 89) felt that therapies for severe DED are not very or not at all effective.

Participants were also asked to provide their opinion of a set of presented statements, including whether more treatment options are needed for moderate to severe DED, treatment of DED can help establish a practice, DED is difficult to diagnose, the signs and symptoms of moderate to severe DED can be improved but seldom eliminated, there is a treatment gap between artificial tears and more aggressive treatments for moderate to severe DED, and multiple therapeutic agents are usually needed to manage moderate to severe DED. As summarized in Table 3, the majority of respondents agreed that more treatment options are needed for moderate to severe DED (94.4%; n = 219). Corneal specialists were more likely to strongly agree (63%) than general ophthalmologists (54%). Participants also agreed that multiple therapeutic agents are usually necessary to manage moderate to severe disease (92.3%; n = 215), that a gap exists between treatment with artificial tears and more aggressive therapy for moderate to severe DED (82.7%; n = 191), and that while signs and symptoms may improve, they are seldom eliminated (81.1%; n = 189). The majority of participants (80.6%; n = 187) disagreed with the statement that DED is difficult to diagnose.

TABLE 3. RESPONDENT LEVEL OF AGREEMENT TO A SET OF STATEMENTS ABOUT DRY EYE SYNDROME

STATEMENT	STRONGLY AGREE (%)	SOMEWHAT AGREE (%)	SOMEWHAT DISAGREE (%)	STRONGLY DISAGREE (%)	TOTAL (N)
More treatment options are needed for moderate/severe dry eye	55.6	38.8	4.7	0.9	232
Multiple therapeutic agents are usually needed to manage moderate/severe dry eye	41.6	50.6	6.4	1.3	233
Treating dry eye can help build my practice	34.8	52.4	9.9	3.0	233
There is a treatment gap between artificial tears and more aggressive moderate/severe dry eye treatments	20.3	62.3	16.0	1.3	231
Signs and symptoms of moderate/severe dry eye can be improved but seldom eliminated	28.8	52.4	17.2	1.7	233
Dry eye is difficult to diagnose	1.7	17.7	53.4	27.2	232

DISCUSSION

The results of this survey provide insight into the current perceptions of moderate to severe DED and its treatment held by comprehensive ophthalmologists and corneal specialists throughout the United States. Only 10 of the 245 participants in this survey (4.1%) indicated that they see fewer than 4 DED patients per month, emphasizing the common clinical presentation of the disease. Consistent with the accepted etiology of DED, respondents confirmed that the disease is indeed multifactorial in nature. DED is a multifactorial disorder of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability and poses a risk of potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface. While environmental conditions of low humidity and postmenopausal hormonal changes were indicated as leading primary causes of DED, systemic medications, use of contact lenses, eye/eyelid injury, Sjögren syndrome, and LASIK or other ocular surgery were identified as major primary causes with approximately equal frequency.

Respondents indicated that successful management of the disease is often measured by patient-reported improvement in symptoms and overall satisfaction. It is of particular interest that although the majority of participants in this survey identify inflammation as an underlying cause of DED, they identify protection of the ocular surface and lubrication of the eye as the most important goals of treatment. Therefore, treatment choices should consider the negative impact of preservatives such as benzalkonium chloride, found in some dry eye solutions. Their effects on the cornea and conjunctival epithelium led members of the Management and Therapy Subcommittee of the Dry Eye Workshop (DEWS) ⁴ to recommend preservative-free ocular lubricants.

As expected, respondents indicated that they prescribe or recommend more treatment options for increasingly advanced DED. The majority of participants stated that current treatment options for patients with severe DED are not effective and that a gap exists between currently available artificial tears and effective therapy. Participants identified a clear need for additional options that provide continuous relief of DED symptoms and that are acceptable to patients. A preservative-free therapeutic option that provided continuous, long-term relief of DED symptoms would be highly desirable.

Data obtained from surveys of this type have inherent biases that should be acknowledged. Respondents were limited to those ophthalmologists who could be reached online, and the percentage of respondents was, as is typical of such surveys, relatively small (3.1%) and may not be entirely representative of the overall population. Despite these limitations, the demographics of the respondent group indicated that respondents were well distributed geographically and were representative of the full range of ophthalmologic practice.

While the results of this survey provide insight into ophthalmologists' current perceptions and treatment of patients with moderate to severe DED, they do not address patients' perceptions of the disease. A future survey to compare patients' responses may provide additional insight due to the general lack of correlation between the signs and symptoms of DED.

ACKNOWLEDGMENTS

Funding/Support: Supported by Aton Pharma Inc, Lawrenceville, New Jersey.

Financial Disclosures: Dr Asbell and Dr Spiegel are consultants for Aton Pharma. Dr Asbell also receives grant support from Aton Pharma

Author Contributions: Design of the study (P.A., S.S.); Conduct of the study (P.A.); Management, analysis, and interpretation of data (P.A., S.S.); Preparation, review, or approval of manuscript (P.A., S.S.).

Conformity With Author Information: An institutional review board waiver was provided to conduct this survey.

Other Acknowledgments: The authors would like to thank Ed Stevens, MEd, for his assistance with developing the survey questionnaire and Norman Nagl, PhD, and Donald Nelinson, PhD, for editorial assistance in preparation of this manuscript.

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PEER DISCUSSION

DR. MARIAN S. MACSAI: This paper reports ophthalmologists' perceptions of the prevalence, causes, and treatments for dry eye disease (DED), as measured by an on line email survey. The targeted respondents were 7882 randomly selected practicing ophthalmologists from the 23,000-subscriber list to *Ophthalmology Times*. The survey was conducted through email inquiries directing the recipient to a web site; entry into a drawing to win a moderate sized prize was used as enticement to participate. Aton Pharma, the producer of LacrisertsTM, provided support for this survey. A total of 245 (3%) surveys were completed and 10 were excluded from analyses because only those reporting treatment of 4 or more moderate to severe cases per week were included. The majority of the respondents were comprehensive ophthalmologists with corneal specialists representing 22%.

It is not clear that this sample is representative of the ophthalmology community as a whole. The results did identify wide geographical representation but 23 (9.4%) respondents were from outside the US or did not specify their location. This group should have been excluded from the analyses as they may have had access to dry eye treatments not available in the United States.

The respondents were queried about their perceptions of the prevalence of different primary causes in their dry eye patient population. The aqueous deficient and evaporative dry eyes were not considered separately. The authors report that 72% of respondents believe inflammation is an underlying cause of DED, and 25% believe that inflammation is a consequence of DED. This highlights the ongoing debate of whether inflammation or DED is the initial insult or the result of an underlying inflammatory process. Survey respondents report maintenance and protection of the ocular surface as their number one goal of treatment. This is not surprising as a healthy ocular surface is necessary for optimal vision and is related to patient symptoms.¹

One interesting validation is that as the severity of DED increases, the number of therapeutic approaches also increases. This is the same recommendation for treatment made in the DEWS report. This trend would lead the reader to believe that symptoms follow the severity ratings of the disease, as clinicians stated that relief of patient symptoms was the number one reason for treating. It is not clear if the differences in number of treatments between severity groups are statistically significant, since neither standard deviations nor statistical analyses are provided. Hence, the conclusions may not be valid, as we do not know if the differences in the reported means were statistically significant.

Research has shown that response rates are higher with electronic surveys than with paper surveys or interviews.² Yet,the response rate in this study is very low, with only 3% of surveys completed. Electronic mail is a large part of our communication system. There are some validity issues to consider in the use of email surveys.² A sample may not truly represent a population, since individuals who have access to the Internet may not be representative of the population. Additionally, there are limitations in data analysis, since researchers do not necessarily know exactly who has responded. This issue challenges the external validity of the study; therefore the authors should avoid using inferential analysis of electronic surveys.

A sampling error arises from the fact that samples inevitably differ from their populations. Survey sample results should be seen only as estimations. A statement of sampling error must contain the confidence level and the confidence interval. These two components are used together to express the accuracy of the sample's statistics in terms of the level of confidence that the statistics fall within a specified interval from the true population parameter. Variance estimates and confidence intervals become greater as the sample size is reduced, and it becomes more difficult to construct confidence limits.³ In this study, neither confidence levels nor confidence intervals were reported.

In summary, the reliability of this study is limited. The individuals surveyed indicated their response, which was valid only for that point in time. It has not been reproduced to demonstrate the answer is reliable. The questions used in the survey have not been validated. Therefore, generalizations about ophthalmologists' perceptions from this study may be neither reliable nor valid. Much of this paper is worded in a way that makes it easy to forget that the data is based on perceptions, which do no always mirror scientific fact. The authors should be cautious about making scientific claims from a perception survey. It is well established that symptoms from DED are one of the most common patient complaints ophthalmologists face. Unfortunately, relatively few treatment options are available for DED and the resulting frustration of physicians was well known prior to this survey.

ACKNOWLEDGMENTS

Funding/Support: None

Financial Disclosures: None

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- DR. ALLAN J. FLACH: How do you define "moderate" and "severe" dry eye?

DR. DOUGLAS D. KOCH: No conflicts of interest. I would just echo the comments about the questionable methods in this study. I have a lot of concerns about a study sponsored by a pharmaceutical company that has a biased patient sample. Also, the questions seem constructed to give responses favorable to the sponsor.

DR. PENNY A. ASBELL: Good comments. Thanks Marian and everybody else. You know it is a survey. Fortunately, we have been hearing a little bit harder science earlier this morning. A survey is a survey and it is difficult to derive a scientific conclusion as we would in a randomized trial. The confidence interval reported by the statistician was +/-6%, so the study does include some statistical information that I did not include in the presentation. Marian did not receive the final version until recently so there was some more statistical analysis, but a survey is a survey. I think it is an interesting question about whether we should have included everyone. The thought was that we wanted ophthalmologists who were interested in dry eye disease and who treated a significant number of patients. I definitely agree there is a bias in picking such patients versus picking from the universe of all patients. I believe that it does alert us to the fact that dry eye disease is a significant part of a patient population that ophthalmologists, primarily in the United States treat; at least as much as a survey can tell us anything Therefore, it is worthy of understanding better and looking at better treatments. Other than that, it is not science. What they believe to be the case does not make it true.

APPENDIX

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Physician Survey of Treatment for Moderate to Severe Dry Eye

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Asbell, Spiegel

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And now	vunronul cellulose
Vour a	, a few questions about you and your practice…
	ender: Male
ä	Female
	h region do you work?
	Northeast (MA, CT, NY, NJ, PA, VT, NH, RI, ME)
	Northwest (OR, WA, ID, MT, WY, AK) Southeast (LA, MS, AL, GA, FL, TN, KY, NC, SC, AR, DE, VA, WV, MD, DC)
	Southwest (CA, HI, AZ, NM, NV, CO, UT, OK, TX)
Please	tell us the length of time you have spent in practice:
	Currently a resident Less than a year
	1-5 years
	6-10 years 11-20 years
	21-30 years
	31-35 years More than 35 years
	indicate your category of practice:
	Corneal specialist
	Other (Please specify)
How ma	any patients do you see each week? Fewer than 50
	50-75
	76-100 101-125
	126-150 151-200
<u> </u>	
	4
	any mild, moderate, and/or severe dry eye patients do you see each week?
	1-5
	6-10 11-20
	21-30
8	31-50 More than 50
opinions of o	r your interest in our survey. At this time, we are seeking the only those ophthalmologists who treat significant numbers of tients with moderate to severe dry eye syndrome.
Please	provide your name and e-mail address to enter in the drawing to win an HDTV
Name:	
E-mail:	
Upon co	ompletion, the server will redirect you to the <i>Modern Medicine</i> homepage