On behalf of Vision Expo, we sincerely thank you for being with us this year.

Vision Expo Has Gone Green!

We have eliminated all paper session evaluation forms. Please be sure to complete your electronic session evaluations online when you login to request your CE Letter for each course you attended! Your feedback is important to us as our Education Planning Committee considers content and speakers for future meetings to provide you with the best education possible.



ABO Basic Exam Review

Domain II: A&P, Refraction Domain VI: Laws, Standards, and Regulations

National Federation of Opticianry Schools

Formal Opticianry Education.... We teach the Why

Presented by Tracy E Bennett, LDO, ABO-AC, NCLEC



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Domain II

- Structures of the Eye and Functions
- Refractive Errors







Sclera

- Is the white opaque fibrous outer tunic of the eyeball that covers 5/6 of the posterior portion of the globe
- Maintains the shape of the eyeball
- It is the outer protective layer of the globe
- It is surrounded by the episclera and conjunctiva
- It contains anterior apertures for drainage and anchorage for the extraocular muscles



General Anatomy of the Eye





Cornea









THE CORNEA

- The adult cornea is only about 1/2 millimeter thick and is comprised of 5 layers:
 - Epithelium
 - Bowman's Membrane
 - Stroma,
 - Descemet's membrane
 - Endothelium



Epithelium

• The epithelium is layer of cells that cover the surface of the cornea. It is only about 5-6 cell layers thick and quickly regenerates when the cornea is injured. If the injury penetrates more deeply into the cornea, it may leave a scar.



Bowman's Membrane

• Bowman's membrane lies just beneath the epithelium. Because this layer is very tough and difficult to penetrate, it protects the cornea from injury. However, if penetrated, it will leave a permanent scar.



Stroma

 The stroma is the thickest layer and lies just beneath Bowman's. It is composed of tiny collagen fibrils that run parallel to each other. This special formation of the collagen fibrils gives the cornea its clarity.



Descemet's Membrane

- Descemet's membrane lies between the stroma and the endothelium.
- It acts like the ground cover controls the amount of fluid flowing back and forth between the stroma and endothelium



Endothelium

• The endothelium is just underneath Descemet's and is only one cell layer thick. This layer pumps water from the cornea, keeping it clear. If damaged or disease, these cells will not regenerate.



Cornea

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Figure 11

Epithelium Bowman's Layer

Stroma

Descemet's Membrane Endothelium



# Choroid









### Iris

• The colored part of the eye is called the iris. It controls light levels inside the eye similar to the aperture on a camera. The round opening in the center of the iris is called the <u>pupil</u>. The iris is embedded with tiny muscles that dilate (widen) and constrict (narrow) the pupil size.





# The Humors'

• The aqueous is the thin, watery fluid that fills the space between the <u>cornea</u> and the iris (anterior chamber). It is continually produced by the ciliary body, the part of the eye that lies just behind the <u>iris</u>. This fluid nourishes the cornea and the lens and gives the front of the eye its form and shape.





## Vitreous

- The vitreous is a thick, transparent substance that fills the center of the eye. It is composed mainly of water and comprises about 2/3 of the eye's volume, giving it form and shape. The viscous properties of the vitreous allow the eye to return to its normal shape if compressed.
- As the vitreous thins, it separates from the retina, often causing <u>floaters</u>.













### Refractive Errors

- Hyperopia
- Myopia
- Presbyopia
- Astigmatism



#### Emmetropia – No Visual Error





## Hyperopia (Hypermetropia)

Rays of light come to focus behind the retina of an unaccommodated eye





# Myopia

• Rays of light come to focus in front of the retina of an unaccommodated eye





# Categories of Astigmatism

- Simple myopic one meridian is plano, the other myopic (-)
- Simple hyperopia one meridian is plano, the other hypermetropic (+)
- Compound myopic both meridians are myopic (-)
- Compound hypermetropic both meridians are hypermetropic (+)
- Mixed one meridian is hypermetropic, the other is myopic ( + and -)



# Types of Astigmatism

#### Refractive types of regular Astigmatism:

A, Simple myopic.

B, Simple hypermetropic.

C, Compound myopic







D, Compound hypermetropic

E, Mixed







#### Simple Myopic Astigmatism

A, Simple myopic.





Simple Myopic Astigmatism

- Simple myopic one meridian is plano, the other is myopic (-)
  - Ex. Plano 2.00 x 180
  - Ex. Plano -1.50 x 180



#### Simple Hyperopic Astigmatism

B, Simple hypermetropic.





Simple Hyperopic Astigmatism

- Simple hyperopic one meridian is plano, the other is hyperopic (+)
  - Ex. Plano + 2.00 x 180
  - Ex. Plano + 3.50 x 180



#### Compound Myopic Astigmatism

# C, Compound myopic





Compound Myopic Astigmatism

 Compound Myopic - Both meridians are myopic



# Compound Hyperopic Astigmatism

D, Compound hypermetropic




Compound Hyperopic Astigmatism

- Compound Hyperopic Both meridians are hyperopic
  - Ex. +2.00 + 2.00 x 180



#### Mixed Astigmatism

E, Mixed





Mixed Astigmatism

- Mixed Astigmatism One meridian is myopic and the other meridian is hyperopic
- Ex. -1.00 +2.00 x 180
  Transposed: +1.00 -2.00 x 090



ABO Domain VI Laws, Regulations, and Standards



#### Agencies

There are a number of industry and government agencies that have a direct impact on the business of eyewear. All are important to the dispenser in ensuring that the wearer is receiving a product that is within the expectations of the ophthalmic industry and government regulatory agencies.



#### The Food and Drug Administration

 The Food and Drug Administration (FDA) began mandating impact resistance of ophthalmic lenses in 1971. Since then, all eyeglass and sunglass lenses must be impact-resistant, except when the optometrist or physician finds that they will not otherwise fulfill the patient's visual requirements.



# The Drop-Ball Test

- With few exceptions, all glass lenses must be hardened and individually subjected to the drop-ball test.
- Glass lenses exempt from testing include the following:
  - I. Raised multifocal lenses (these are lenses that have a ledge area on the lens, such as an Executive lens)
  - 2. Prism segment multifocals
  - 3. Slab-off lenses
  - 4. Lenticular cataract lenses
  - 5. lseikonic (size) lenses
  - 6. Depressed-segment one-piece multifocals
  - 7. Biconcave myodisc, and minus lenticular lenses
  - 8. Custom laminate lenses (e.g., Corlon lenses)
  - 9. Cement assembly lenses





- The standard for determining impact resistance is the Drop Ball test
- Lens must be placed on a neoprene gasket and a 5/8" steel ball weighing 0.56 oz is dropped from a height of 50 inches
- Basic Impact Testing results should be kept for 3 years from purchase



# Batch Testing of Lenses

- Batch Testing is the practice of selectively testing a statistically significant number of lenses in a manufactured group. This avoids having to individually test lenses that could sustain damage by the test itself. The practice of batch testing is permitted for the following:
  - Hard Resin Lenses
  - Nonprescription lenses such as mass-produced sunglass lenses.( it should be noted that glass, plano sunglass lenses individually produced in a finishing laboratory must still be individually dropball tested.
- The manufacturer is responsible for testing, even when the plastic lenses are later edged by someone else, as in the case of an in-house finishing laboratory.



# Heat Treating

- Heat treating is done by placing an edged glass lens into a small kiln where the temperature is high enough to almost bring the glass to the softening point.
- The exact time depends on: Lens thickness, Type of glass and lens tint
- Lens is removed from the heat and cooled rapidly



#### Heat Treating





#### Polariscope or Colmascope

- Has two crossed polarizing filters that shows Maltese-cross pattern
- Also used to check strain and pressure points in a plastic or metal frame





#### Heat Treated Lens Pattern (Maltese Cross Pattern)





# Chemical Tempering Process



- Glass lenses are chemically hardened by immersing them in molten salt. Lenses are preheated
- During the process of chemical tempering, smaller sodium (Na) or Lithium (Li) ions are drawn out of the lens surface and replace by large potassium (K) ions from the salt
- This squeezes the lens increasing impact resistance by creating compressive stress
- Heat temperature for glass is 842° F
- Lenses are removed and then allowed to cool at room temperature, then rinsed in hot water to remove the salt



#### Chemical Treating Units





# Identifying a Chemical

- Ype mystane the lens out of the frame and immerse it in glycerin solution while viewing it under a Polariscope or Colmascope
- A chemically hardened lens will show a halo like, bright band around the edge of the lens



# Heat Treated vs. Chemical

- Tempering Chemical Tempered lenses are <u>more</u> impact resistance than Heat Treated lenses
  - Lenses that are chemical tempered will not warp like some heat treated lenses do
  - Chemical tempering maintains their impact resistance even if scratched and can be re-edged without breaking



# The Dispenser's Role in Record Keeping

- To ensure that all regulations have been met and that ophthalmic lenses are safe, the FDA requires that records be kept for 3 years after the purchase of eyeglasses.
- Information that must be kept consists of records of the sale or distribution of prescription eyewear, including the names and addresses of people buying prescription eyewear (records do not have to be kept for individuals buying nonprescription eyewear).



#### Federal Trade Commission

- The Federal Trade Commission (FTC) was established to prevent unfair business practices such as deceptive advertising and monopolies.
- The FTC began to look at the ophthalmic industry. After two series of investigative studies known as Eyeglasses I and Eyeglasses II, prescription release rules were formulated for spectacle and contact lenses.



# Eyeglasses I

- In 1978, the FTC concluded their Eyeglasses I investigative study with a spectacle lens Prescription Release Rule.
- This rule requires that patients be given 2 copies of their spectacle lens prescription so that they may fill that prescription wherever they desire.
- The prescription is to be given immediately after the eye examination is completed, whether or not the patient asks for the prescription



# Eyeglasses I

- A new written prescription is also to be given even if the change is too small to require a change in eyeglasses or if there is no change at all since the previous eye examination.
- The Eyeglasses I Prescription Release Rule listed minimum information to be included in the prescription: sphere power, cylinder power and axis (if any), prism (if any), and the signature of the prescribing doctor.



#### Eyeglasses II

- Eyeglasses II (1989) no longer lists minimal information needed for spectacles lens prescriptions
- Prescribers are at liberty to include whatever they consider important for the patient's visual welfare
- Could include: lens material, lens styles, and instructions
- An expiration date is usually part of the prescription



# **Principles of Informed Consent**

• You must provide the patient with enough information so that he or she can make a reasonable decision



# Contents of Informed Consent Document

The Patient must understand the following:

- Risks of procedure, including loss of vision
- Benefits of procedure
- Complications
- Alternative treatments
- Explanation of procedure
- Advantages of one procedure over another
- Significant issues (e.g. Monovision, Glass vs. Polycarbonate)



# **Duty of Disclosure**

- To frankly answer questions about the risk.
- To disclose the benefits and advantages of the procedure.
- To disclose alternative procedures available and their risks.
- The probability of success.



# **Product Liability**

- This is the generic term used to describe the liability of a supplier of a product to one injured by the product
- . Informed Consent / Duty to Disclose
- The Law considers Inadequate Warning a product defect – Duty to Disclose
- Misuse of the product by the patient is not a defense for Product Liabiliy



# American National Standards

- Institute
   The American National Standards institute (ANSI) is an industry-based standards-setting agency. ANSI in not only an agency for ophthalmic matters; it also addresses standards throughout all of industry, of which the ophthalmic industry is only a small part.
- Some state licensing agencies have adopted ANSI Standards as state law



ANSI sets standards for things that include, but are not limited to:

- prescription ophthalmic lenses (ANSI Z80. 1)
- dress ophthalmic frames (ANSI Z80.5)
- safety eyewear (ANSI Z87.1)
- rigid contact lenses (ANSI Z80.2)
- soft contact lenses (ANSI Z80.8)
- nonprescription sunglasses and fashion eyewear (ANSI Z80.3)
- low-vision aids (ANSI Z80.9)



#### OptiCampus ANSI Z80.1-2015 Summary

General Tolerances for Single Vision and Multifocal Lenses		
Measurement	Power Range	Tolerance
Sphere Power	≥ 0.00 D, ≤ ±6.50 D > ±6.50 D	±0.13 D ±2%
Cylinder Power	≥ 0.00 D, ≤ 2.00 D > 2.00 D, ≤ 4.50 D > 4.50 D	±0.13 D ±0.15 D ±4%
Cylinder Axis	<ul> <li>&gt; 0.00 D, ≤ 0.25 D</li> <li>&gt; 0.25 D, ≤ 0.50 D</li> <li>&gt; 0.50 D, ≤ 0.75 D</li> <li>&gt; 0.75 D, ≤ 1.50 D</li> <li>&gt; 1.50 D</li> </ul>	±14° ±7° ±5° ±3° ±2°
Add Power	≤ +4.00 D > +4.00 D	±0.12 D ±0.18 D
Unmounted Prism and PRP	≥ 0.00 D, ≤ ±3.37 D > ±3.37 D	0.33 Δ 1.0 mm
Vertical Prism Imbalance	≥ 0.00 D, ≤ ±3.37 D > ±3.37 D	±0.33 ∆ Total ±1.0 mm Difference
Horizontal Prism Imbalance	≥ 0.00 D, ≤ ±2.75 D > ±2.75 D	±0.67 ∆ Total ±2.5 mm Total



#### OptiCampus ANSI Z80.1-2015 Standard

Measurement	Comment	Tolerance
Center Thickness	When Specified	±0.3 mm
Base Curve	When Specified	±0.75 D
Segment Size	For Multifocals	±0.5 mm
Warpage		1.00 D

Vertical Fitting Point Height	±1.0 mm Each
Vertical Fitting Point Difference	1.0 mm Difference



# ANSI **Z87.1 2015**

Most recent update version:

- Two types: Basic Impact and High Impact
- Basic
  - 3 mm minimum thickness
  - 1 inch steel ball 50 inches
  - Must have safety markings
  - Warning that not recommended for high impact exposure.
- High Impact Requirements
  - Minimum thickness 2.0mm (Poly and Trivex)
  - 3mm for Crown glass and CR-39
  - Must pass ¼ inch steel ball traveling 105 feet/sec
  - Must have plus symbol(+) not just the manufactures logo



# Safety Frames – **Z87**

- In 1989, the standards went to performance based
- Must pass tests not required of dress frames
- High velocity test
- High mass test
- Frame marked Z87 for basic Z87-2 high impact on the front and temples.



#### Safety Frames

- 1989, ANSI dropped specific design requirements and made the requirements more performance based
- High velocity impact test a series of one-fourth inch steel balls traveling at 150 ft / sec are directed at 20 different parts of the <u>glazed</u> frame
- High Mass impact test a pointed conical-tipped projectile, 1 inch in diameter weighing 17.6 oz is dropped 51. 2 inches through a tube onto to the eyeglasses
- The lens must not break or come out of the frage

# Marking Safety Frames – Z87-2

- The "2" signifies that the frame is suitable for 2 mm lenses
- All frames that are marked Z87-2 must be capable of retaining both basic impact of 3.0 mm lenses and 2.0 high impact lenses
- New safety frames can be expected to bear Z87-2 markings
- Safety frames should only be used with safety lenses
- Under no circumstances should a pair of lenses be marked as safety and placed in a non-safety frame



#### Side Shields

- Maybe removal or permanent
- Permanent offers best protection and least liability
- Usually not interchangeable



# American Society for Testing and Materials (ASTM)

- An increase in litigation due to eye injuries has served to raise the consciousness of eye care practitioners, who are now more aware of the need for providing appropriate information on eye protection customized to patient needs.
- American Society for Testing and Materials (ASTM) standards for eye protectors for racquet sports players, although there are other standards for head protection, such as the use of helmets and masks, that may provide a form of eye protection.
## **ASTM Standards**

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ASTM Standards Applicable to Ophthalmic Dispensing

#### ....

Standard Identification Number	Year of Revision	Sports Covered by the Standard
ASTM F513	2000	Standard specification for eye and face protective equipment for hockey players
ASTM F659	1998	Standard specification for skier goggles and face shields
ASTM F803	2003	Standard specification for eye protectors for selected sports
		These sports are listed as racquet sports (such as racquetball, badminton, and tennis), women's lacrosse, field hockey, basketball, baseball, and soccer
ASTM F910	2004	Standard specification for face guards for youth baseball
ASTM F1587	1999, reapproved 2005	Standard specification for head and face protective equipment for ice hockey goaltenders
ASTM F1776	2001	Standard specification for eye protective devices for paintball sports



# ASTM Product Marking

- The manufacturer's identity marking
- Label or Tag with the following information
  - Week and Year of the manufacture
  - Protector size and guidance concerning age and gender
  - Statement on the package as to the sport or sports for which the protector is designed
- Specific Warnings to accompany the ASTM approved eyewear













#### SAFETY EYEWEAR FOR WORK OR PLAY

Occupational Safety and Health Administration (OSHA)

- Federal agency charged with regulating safety practices in the work place.
- ANSI Z87.1 standards were adopted by OSHA so they are federal requirements.
- "protective eye and face equipment shall be required where there is a reasonable probability of injury that can be prevented by such equipment."



The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

 HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The Centers for Medicare & Medicaid Services (CMS) is responsible for implementing various unrelated provisions of HIPAA, therefore HIPAA may mean different things to different people.



#### Malpractice and Professional Liability

All professionals are at risk to accusations of malpractice and consequent lawsuits by disgruntled patients or patients who have suffered some injury. The possibility of a malpractice suit haunts every health care practitioner. As an optician, you need to be knowledgeable and aware of malpractice suits and decisions that might affect you.



Malpractice and Professional Liability

The allegations of negligence require that the defendant didn't conform to the standard of care expected of the professional acting under the same or similar circumstances. The most common source of claims alleging negligence are:

- Failure to prescribe the correct lens material.
- Failure to warn of the danger of breakage.
- Failure to inspect and verify lens orders.

You must be also able to produce documentation, you have perform your job to the standards of the day.

It is the duty of the optician to fully educate the patient as the correct use and wearing of the ophthalmic devices they are purchasing.



#### Dispensers Obligation and Liability

- Recommend the most appropriate material for the patient and document
- "Duty to Inform" is a professional responsibility
- Inform patient about decreased impact resistance of other materials compared with the most suitable material
- Make sure materials received are in compliance with standards required



## Lawsuits

- Lawsuits involving eyewear usually occur on the basis of product liability and negligence
  - Product Liability the product was not up to accepted standard and depends on the type of eyewear
  - Negligence Practitioner did not conform to the standard of care and "Duty to Inform"



## Thank You

Good Luck on the ABO

• For more information, contact the NFOS or visit our website at <u>www.nfos.org</u>

• Power-point by Professor Robert J. Russo – Email: <u>information@nfos.org</u>

