




# Ophthalmic Applicators



# Pterygiumis - Treatment

- Pterygiumis is a Benign Eye Disease that responds to radiation
- Treatment Modalities:
  1. Surgery
  2. Radiation treatment utilizing Sr-90 Beta Ophthalmic Applicator



# Post Op Brachytherapy

- Reduces Recurrence after Surgical Excision
- Post-Op Waiting Time
- Dose Fractionation Scheme



# Roles of Professionals

- After an ophthalmologist makes the diagnosis of pterygium, he/she refers the patient to a radiation oncologist for consultation.
- When 90-Sr eye applicator treatment is chosen as a treatment modality post surgery, the physicist participates in and organizes
  - treatment planning tasks
  - quality assurance of treatment delivery
  - radiation safety procedures



# Introduction

- Normal Eye Anatomy
- Benign Pterygium Eye
- Sr-90/Y-90 Eye Applicator

# Eye Anatomy

- Outer Layer

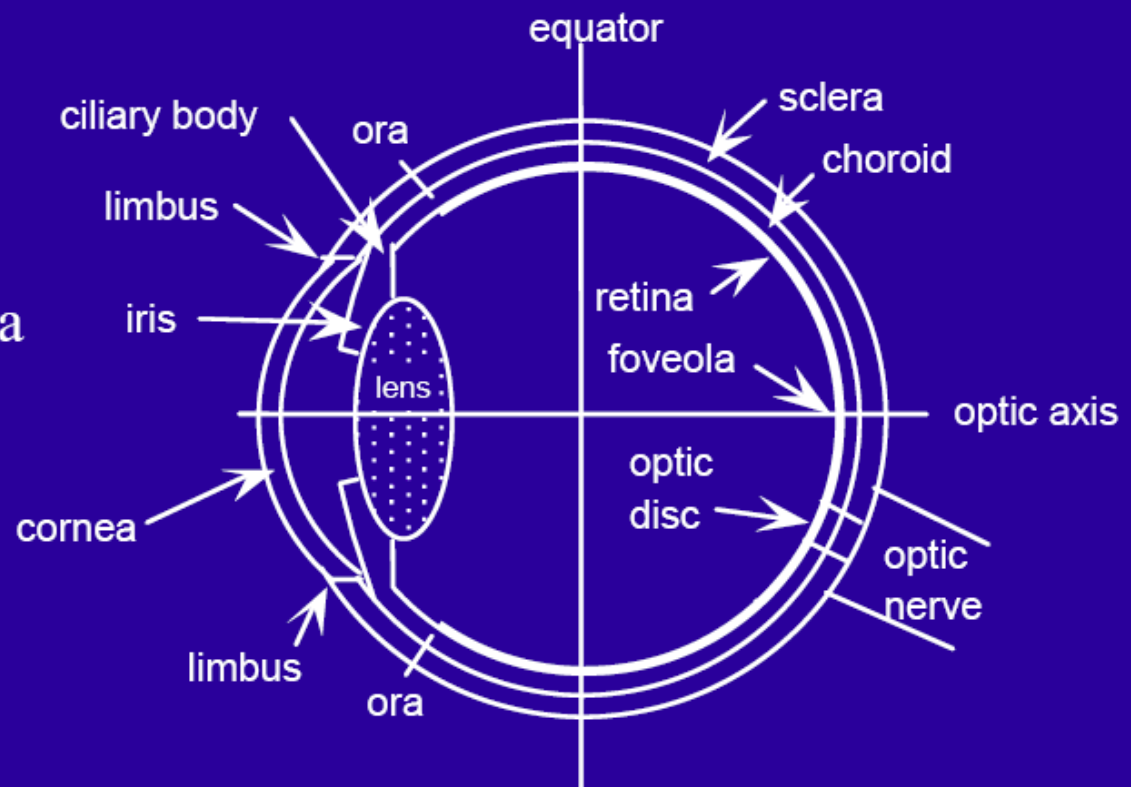
- Sclera
- Cornea

- Middle Layer - Uvea

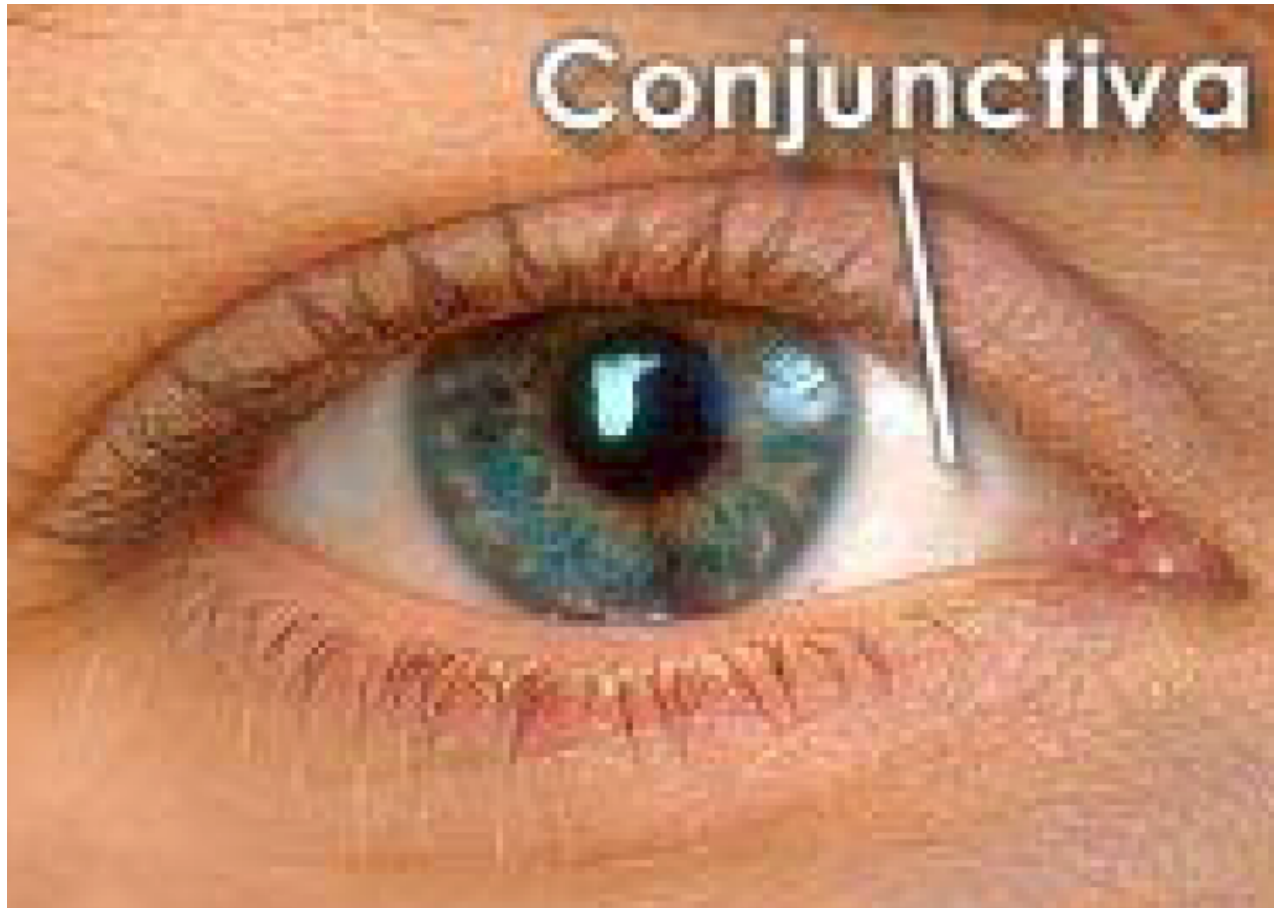
- Choroid
- Ciliary Body
- Iris

- Inner Layer

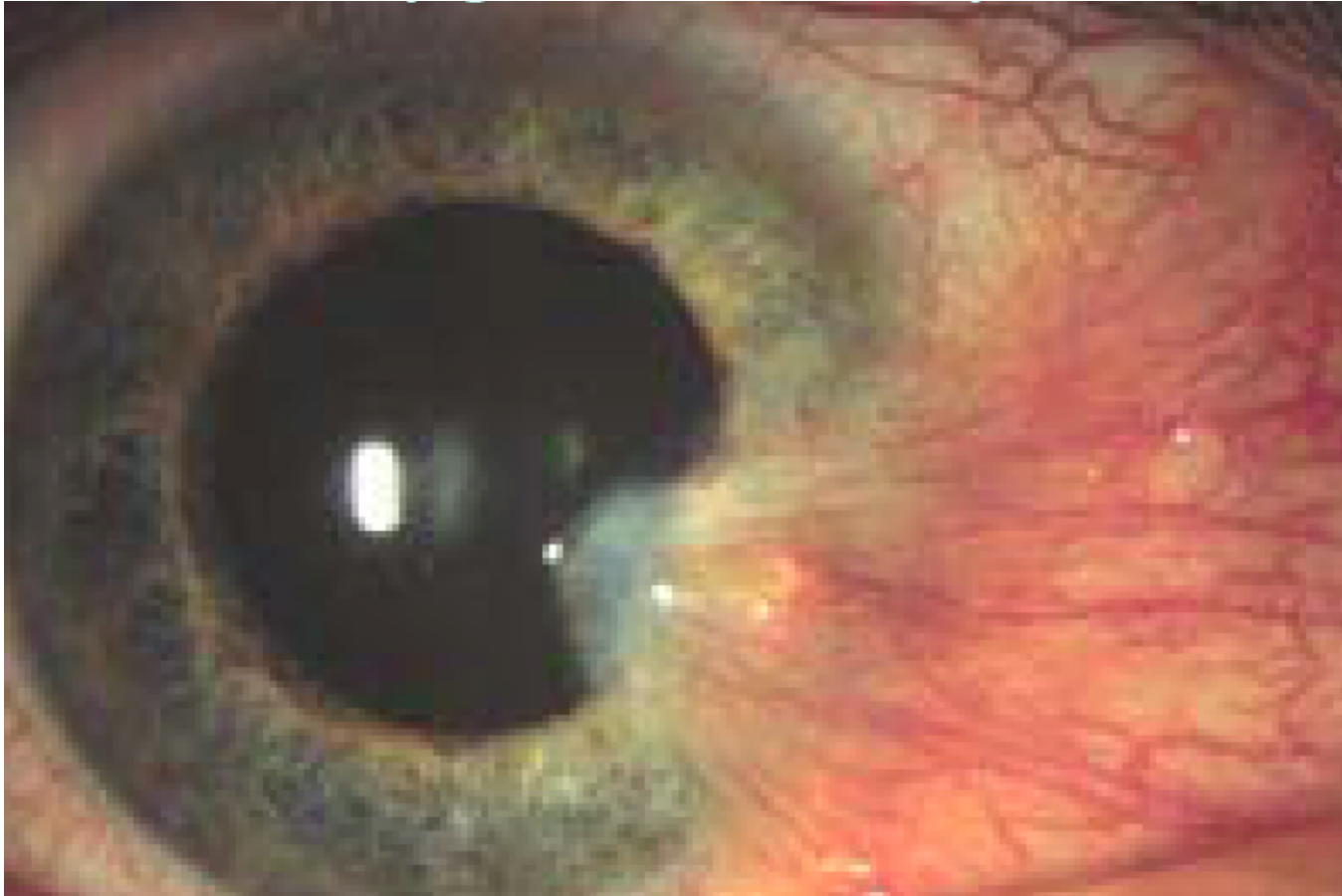
- Retina



# Normal Eye



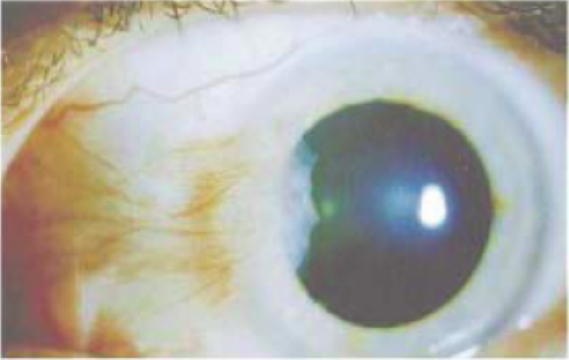
# Pterygium in Eye







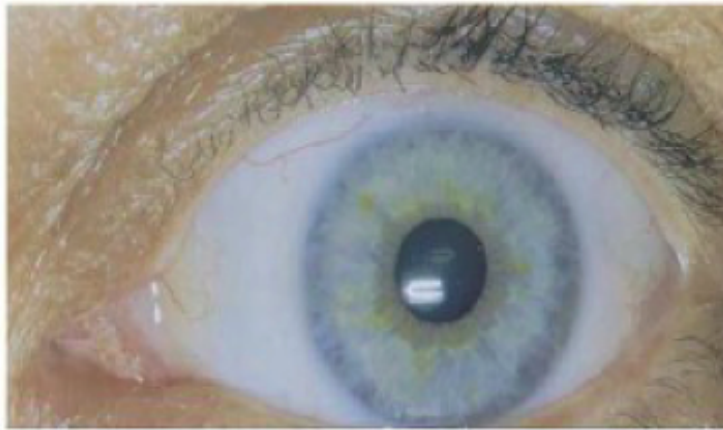
# With Radiation      No Radiation

<p>Primary untreated pterygium left eye</p> 	<p>Primary untreated pterygium left eye</p> 	<p><i>Pre-Op</i></p>
<p>Same eye 6 weeks after combined treatment</p> 	<p>Same eye 6 weeks after excision only, post-operative granuloma</p> 	<p><i>6 weeks</i></p>

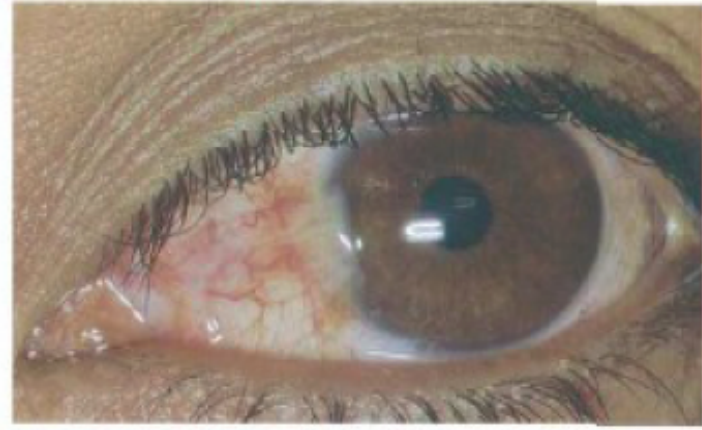
# With Radiation

# No Radiation

Same eye 2 years after combined treatment  
Neither relapse nor complications



Same eye 2 years after excision only,  
pterygium relapse



# Dose Fractionation Schemes

Table 4. Radiation schedules recurrence rates and BED values

Author	Patients (n)	Fractions (n)	Dose per fraction (Gy)	Total dose (Gy)	Overall time (d)	Recurrence (%)	BED3	BED3 RF 1.5	BED10	BED10 RF 1.5	BED25	BED25 RF 1.5	BED35	BED35 RF 1.5
Pajic <i>et al.</i> (41)	97	4	12.5	50	20	2	258.3	228.3	112.5	82.5	75.0	45.0	67.9	37.9
Smith <i>et al.</i> (30)	35	5	5	25	4	5.8	66.7	60.7	37.5	31.5	30.0	24.0	28.6	22.6
Monteiro-Grillo <i>et al.</i> (2)	20	3	10	30	4	5.4	130.0	124.0	60.0	54.0	42.0	36.0	38.6	32.6
Monteiro-Grillo <i>et al.</i> (2)	80	6	10	60	35	19	260.0	207.5	120.0	67.5	84.0	31.5	77.1	24.6
Nishimura <i>et al.</i> (31)	367	4.5	8.9	40	25	11.8	158.7	121.2	75.6	38.1	54.2	16.7	50.2	12.7
Fukushima <i>et al.</i> (9)	391	1	30	30	20	8.6	330.0	300.0	120.0	90.0	66.0	36.0	55.7	25.7
Amano <i>et al.</i> (32)	61	2	10.8	21.6	9	23	99.4	85.9	44.9	31.4	30.9	17.4	28.3	14.8
Schultze <i>et al.</i> (33)	49	5	6	30	4	8.6	90.0	84.0	48.0	42.0	37.2	31.2	35.1	29.1
Parayani <i>et al.</i> (34)	677	6	10	60	35	1.7	260.0	207.5	120.0	67.5	84.0	31.5	77.1	24.6
Wilder <i>et al.</i> (1)	284	8	3	24	13	12	48.0	28.5	31.2	11.7	26.9	7.4	26.1	6.6
de Keizer (7)	18	3	10	30	13	0	130.0	110.5	60.0	40.5	42.0	22.5	38.6	19.1
Present study	44	1	25	25	0	6.8	233.3	233.3	87.5	87.5	50.0	50.0	42.9	42.9
MacKenzie <i>et al.</i> (35)	685	1	22	22	0	12	183.3	183.3	70.4	70.4	41.4	41.4	35.8	35.8
Beyer (36)	127	1	30	30	0	10.2	330.0	330.0	120.0	120.0	66.0	66.0	55.7	55.7
Wesberry and Wesberry (37)	171	1	20	20	0	8	153.3	153.3	60.0	60.0	36.0	36.0	31.4	31.4
Smith <i>et al.</i> (30)	52	5	5	25	4	5.8	66.7	60.7	37.5	31.5	30.0	24.0	28.6	22.6
Alaniz-Camino (38)	483	4	7	28	4	4.3	93.3	87.3	47.6	41.6	35.8	29.8	33.6	27.6

Abbreviations: BED = biologically effective dose in Gray; RF = repopulation factor in Gray per day; BED3, 10, 25, 35 = BED with  $\alpha/\beta$  of 3, 10, 25, 35 Gy.



# Dose Fractionation Scheme

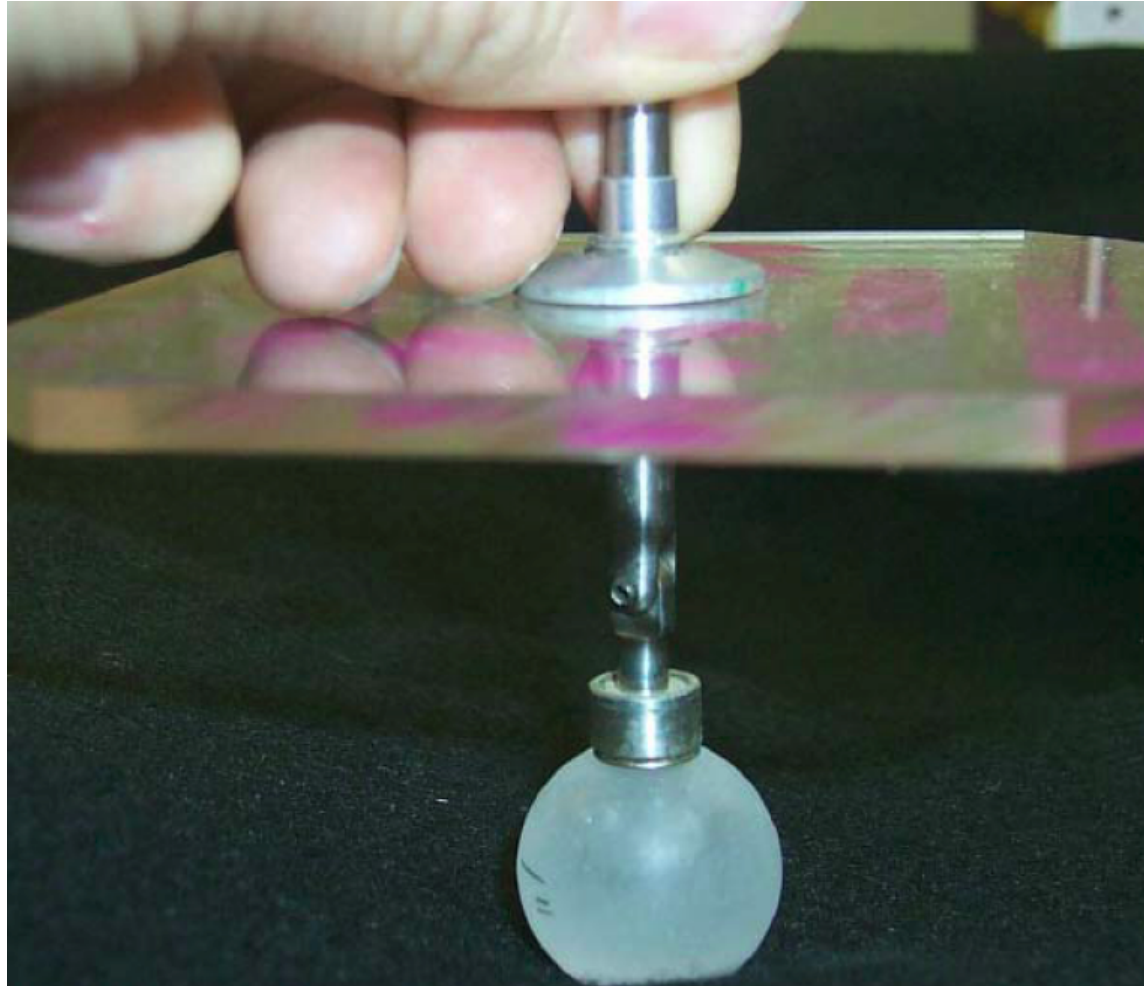
- Total Dose 20 to 60 Gy
- Dose per fraction 3 to 30 Gy
- Number of fractions
  - 1 to 8 fractions



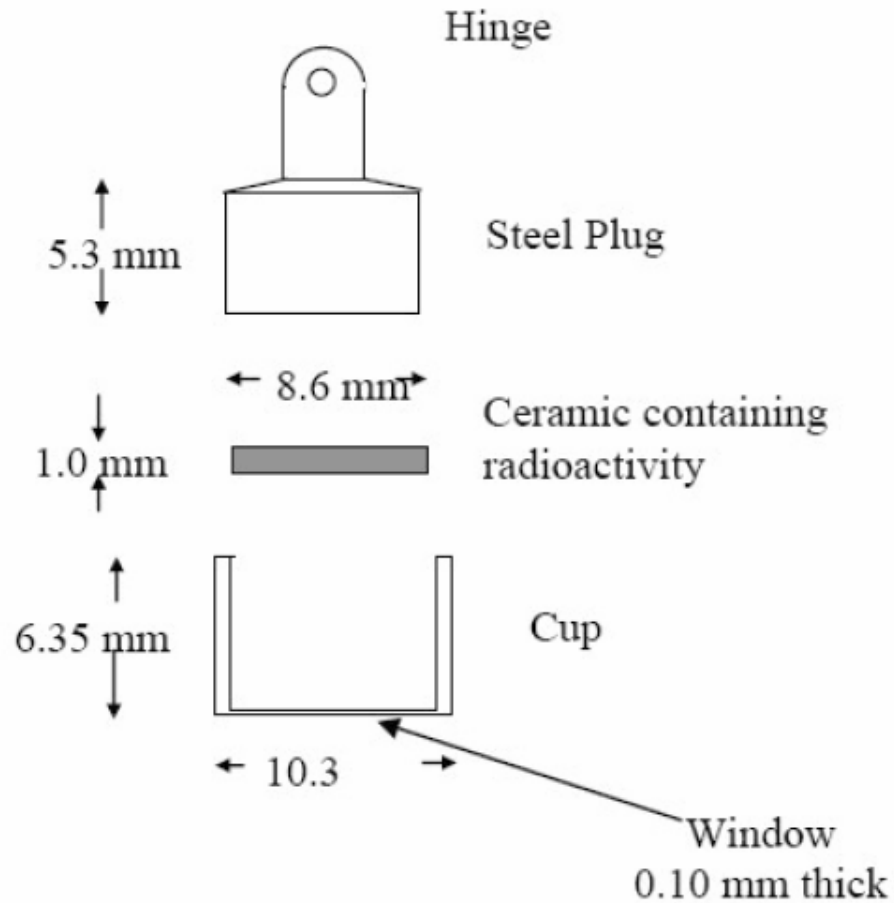
# Sr-90 Ophthalmic Applicator

- Beta Emitter
- Energy: Maximum 2.27 MeV
- Half Life: 28 Years
- Planar Geometry
  - Flat
  - Curved
- Many Sr-90 Eye Applicators were manufactured a few decades ago

# Film Phantom



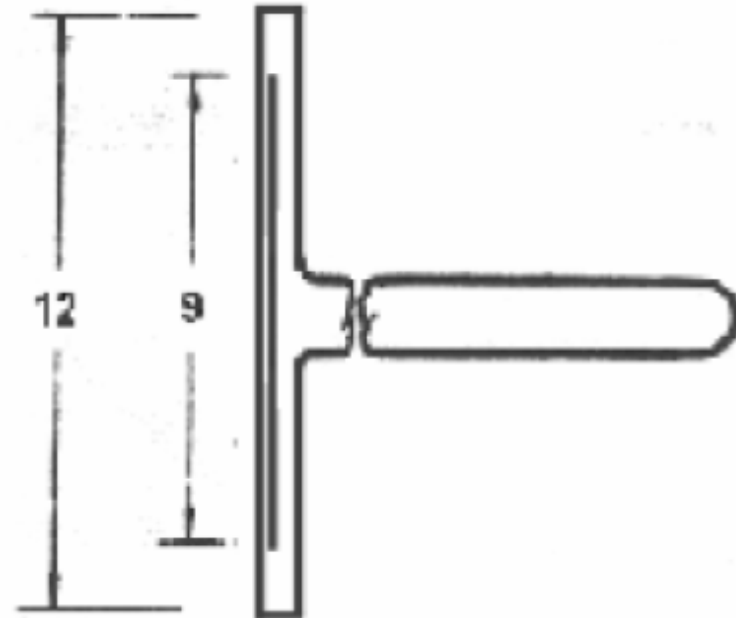
# Schematics of Applicator





# Flat Eye Applicator

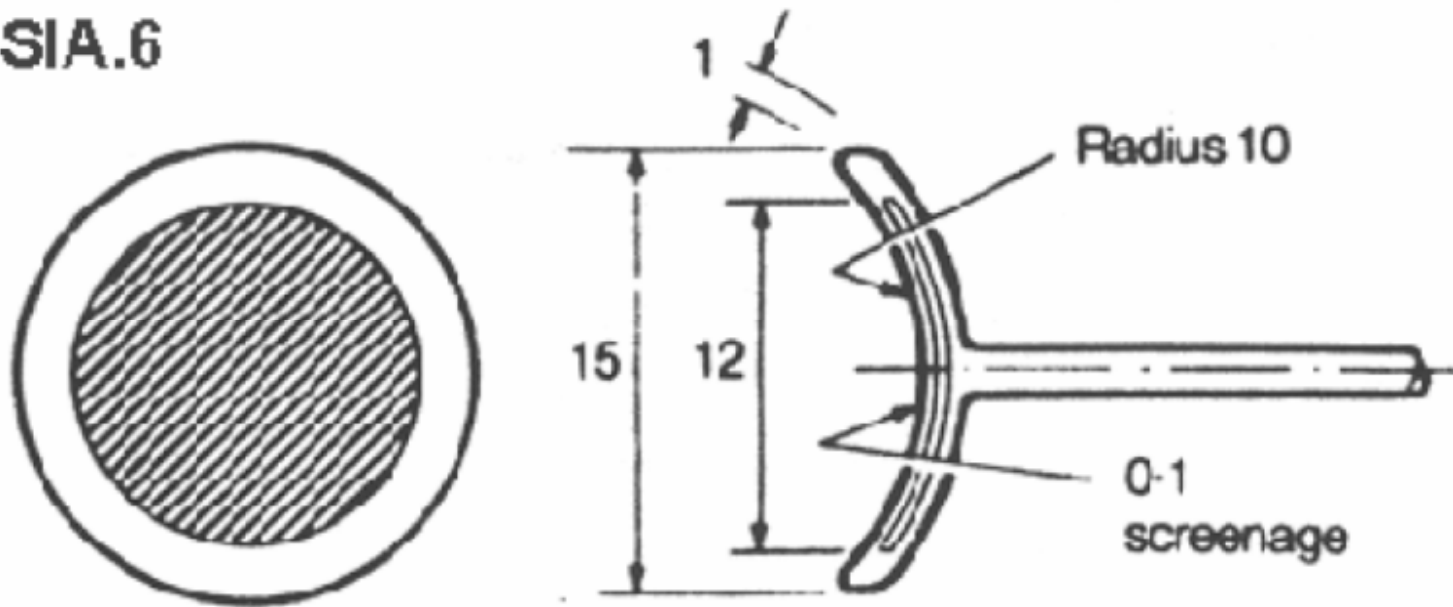
SIA.20





# Curved Applicator

SIA.6





# Surface Doserate Calibration

New Sr-90 applicators typically contain a 2 gigabecquerel (GBq) [54 millicurie (mCi)] source, exhibiting a surface dose rate of about 0.50 Gy (50 rad)/sec.



# Surface Dose Rate Calibration

The half-life of the parent Sr-90 is 28.5 yrs [maximum beta energy equal to 0.54 mega-electron volts (MeV)], and the yttrium-90 (Y-90) daughter half-life is 64.2 hrs (beta-max, 2.27 MeV); therefore, both isotopes are in equilibrium on the eye applicator.



# Surface Dose Rate Calibration

Since Sr-90 and Y-90 are in equilibrium, emissions from both isotopes must be accounted for in dosimetry calculations.

# Surface Doserate Calculations

The dose rate  $D(t)$  at a time  $(t)$ :

(Equation 1) 
$$D(t) = D(o) \times df$$

"decay factor",  $df = - \exp [0.693(t/T_{1/2})]$

"half life" =  $T_{1/2} = 28.5$  yrs

$$df = - \exp[(0.693/28.5 \text{ yrs}) t] = 0.0243 \text{ yr}^{-1}$$

(Equation 2) 
$$df = - \exp[(0.0243 \text{ yr}^{-1}) t]$$

The fraction of activity remaining after a given number of years from the original measurement date is given in Table X



# Surface Doserate Calculations

For example:

An eye applicator calibrated January 1, 1978 has an initial dose rate  $D(o)$  of 0.75 Gy/sec or 75 rad/sec). On January 1, 1996, day of treatment the elapsed time is 18 years.

from Table X,  $df = 0.646$  for Sr-90.

Using formula (Eq1):

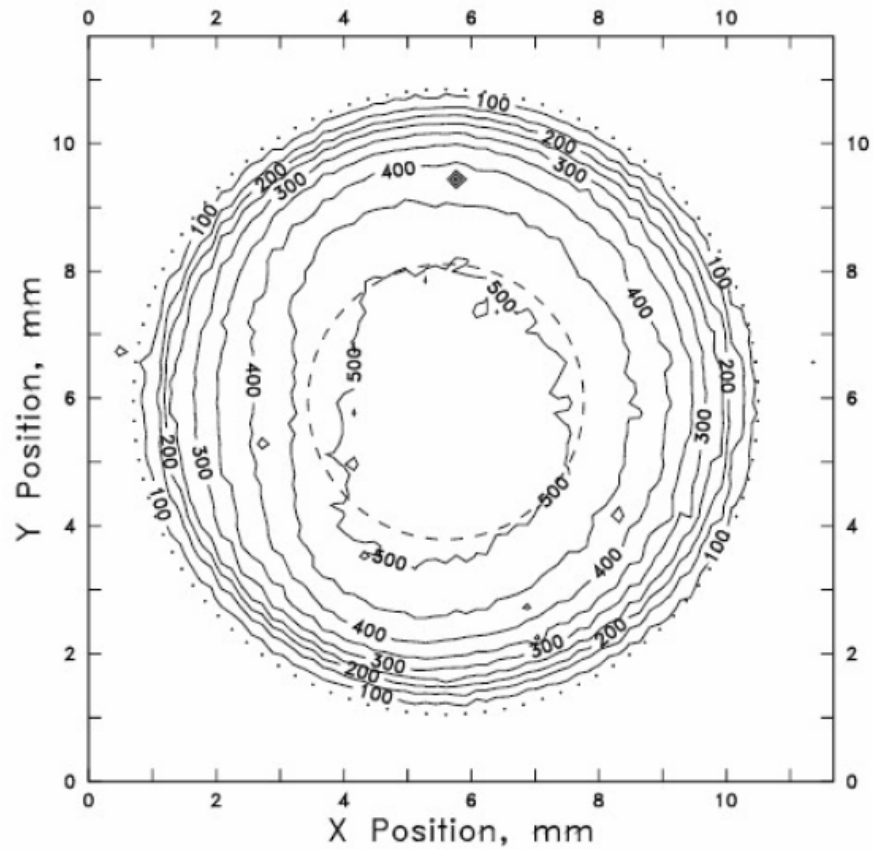
$$D(t) = D(o) \times df$$

$$D(18 \text{ years}) = (0.75 \text{ Gy/sec})(0.646)$$

$$D(18 \text{ years}) = 0.485 \text{ Gy/sec or } 48.5 \text{ rad/sec)$$

(ref NIST 2002)

# Isodose Curves at Applicator Surface



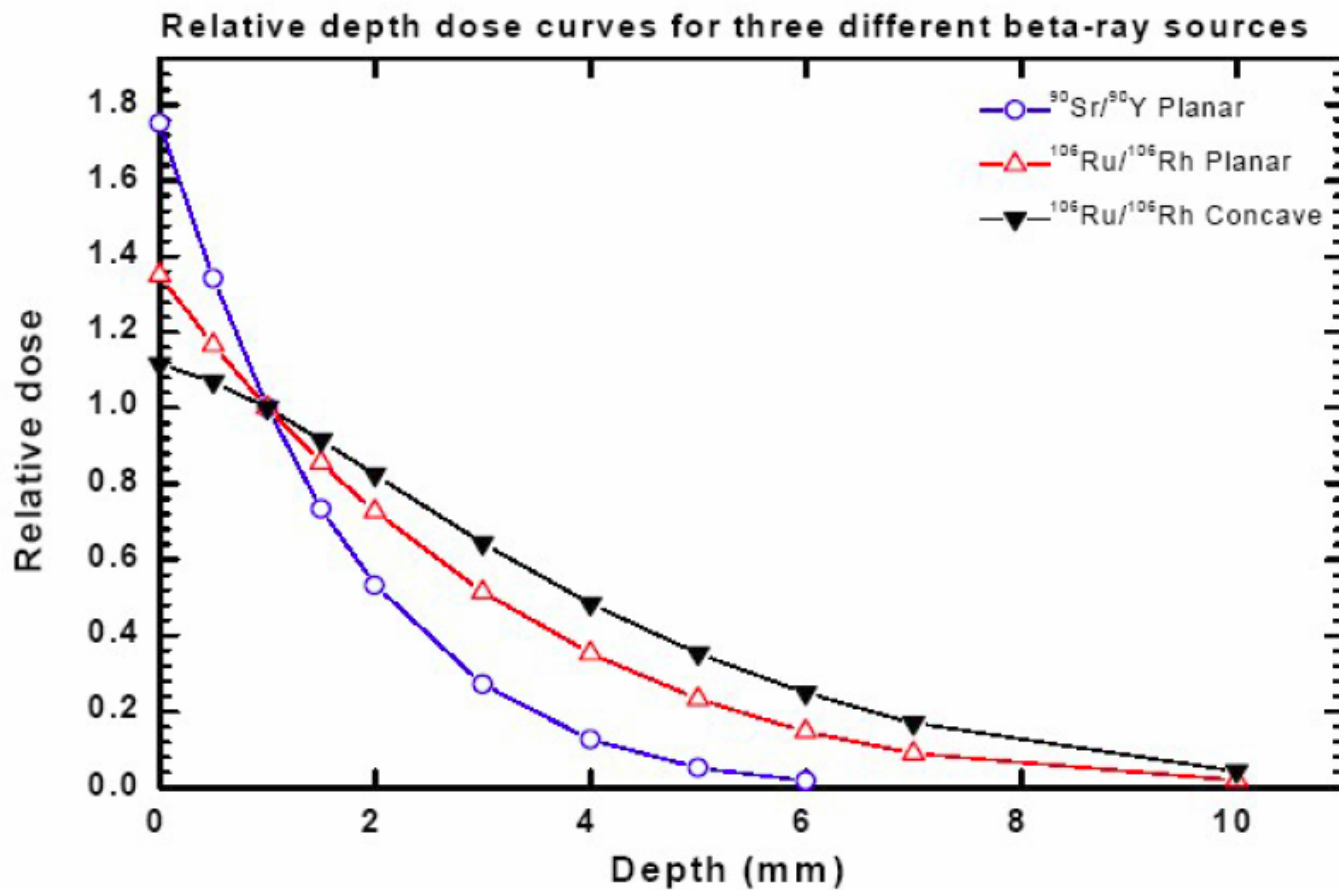


# Surface Dose Rate

- Surface dose rate was about 1 Gy/sec at the time of manufacture
- The surface dose rate in the central area of 4 mm diameter is reported in the calibration report
- High Dose Rate (HDR)
- Surface dose rate varies widely by model



# Depth Dose Curves Along Central Axis





# Dose Calibration Services

- National Institute of Standards and Technology (NIST) (see example calibration in handouts)
- Accredited Dose Calibration Lab (ADCL) in University of Wisconsin



# Dose Calibration Services

- Calculation of the emission rate
- Mapping of the  $^{90}\text{Sr}$  distribution across surface of the applicator in order to ascertain uniformity of dose using:
  - Extrapolation chamber and
  - Radio chromic film dosimetry
- *For further information on the NIST calibration method see NIST procedure in Handouts*



# Treatment Planning

- Prescription dose per fraction and total dose at the applicator surface is written signed and dated on the patient chart by the radiation oncologist (Authorized User)
- Treatment Time is generally calculated manually using a calculator based on the calibrated surface dose rate on the day of application (incorporating decay) by a physicist or dosimetrist(?)
- Double checked by a second physics team member
- The calculation and double check are documented in the patient chart.



# Treatment Time

- Short
- Several Seconds

Example:

- Dose rate: 0.6 Gy/sec
- Dose per fraction: 10 Gy
- Treatment time: 17 sec



# Treatment Delivery

- Treatment delivery is carried out by a team
  - Radiation Oncologist
  - Physicist
  - Dosimetrist
  - Nurse
- Before the application of the eye applicator, the nurse would prepare the patient and help the patient lying supine on a treatment table.



# Treatment Delivery

- Radiation Oncologist holds the applicator and positions the applicator surface on the target site of pterygium for the duration of the calculated treatment time to deliver the prescribed dose.
- The treatment delivery time can be based on a stop watch held by a physicist, dosimetrist or a nurse. This delivery time should be double checked by using another digital timer.



# Quality Assurance

- The dose rate calibration is performed and reported by NIST or ADCL.
- The Written Directive is completed and filed in the treatment chart and given to physicist for calculation of treatment time.
- The treatment time is calculated according to the prescription dose and dose rate (incorporating decay) as calibrated by NIST or ADCL.





# Quality Assurance

- The treatment time calculation is double checked and properly documented.
- The patient's identity is checked prior to treatment delivery using at least two different methods.
  - The treatment site is verified according to the surgeon's report.
  - The treatment delivery time per fraction is monitored, using proper timer device(s).
  - The treatment delivery record is properly documented.
  - The patient post brachytherapy survey is documented



# Regulatory Guidelines

- NRC Information notice 94-17 on March 11, 1994
- Establish a Quality Management Program (QMP) on the use of  $^{90}\text{Sr}$  eye applicator in the treatment of superficial eye conditions.
- The submitted QMP should include written policies and procedures that meet the five objectives, as described in 10 CFR 35.32(a)




# NRC Informed Licensees in 1994

- (1) Researchers at the NIST recognized large discrepancies among calibrated outputs assigned to <sup>90</sup>Sr eye applicators;
- (2) Original manufacturer calibrations were expressed in older (traditional) units, which differed from the System Internationale (SI) units;



## NRC Informed Licensees in 1994

- (3) Calibration values were not comparable for units from different manufacturers; and
- (4) Discrepancies larger than 10% could exist when comparing output measurements between competent measurement laboratories using state-of-the-art techniques.



# Two Optional Approaches Recommended by the NRC

- Option 1
  - Maintaining the same treatment regimen
  - Revising total dose in the written directive.
- Option 2
  - Changing the treatment regimen –
  - Retaining the same written directive total dose value.



## Option 1, Example

*Maintaining the same treatment regimen*

*Revising total dose in the written directive*

- Based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 Gy/s, but the exposure rate based on the new calibration certificate is really 0.55 Gy/s, a value 31% higher.
- The authorized user's medical experience is that the treatment times used in the past provided good medical results.
- To achieve the same medical results, the authorized user would keep the administration time the same and increase the value of the total dose documented in the written directive by 31%.



## Option 1, Example

*Maintaining the same treatment regimen*

*Revising total dose in the written directive*

10 Gy / fraction (previously intended)

0.42 Gy / sec (previously believed)

24 sec (provided good medical results)

0.55 Gy / sec (new calibration certificate)

24 sec (retain the same treatment time)

13.1 Gy / fraction (increase the dose)



## **Option 2, Example**

### ***Changing the treatment regimen***

### ***Retaining the same Written Directive total dose***

- Based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 Gy/s, but the exposure rate based on the new calibration certificate is really 0.55 Gy/s, a value 31% higher.
- The authorized user decides to keep the total dose value the same in the written directive.
- To achieve the same value for the total dose, the authorized user would have to reduce the administration time by 31%.





## Option 2, Example

### *Changing the treatment regimen*

### *Retaining the same Written Directive total dose*

10 Gy per fraction

0.42 Gy/sec (previously believed)

24 sec

10 Gy per fraction (retain the same dose)

0.55 Gy/sec (new calibration certificate)

18 sec (shorter treatment time than before)

**Warning:** Changing the treatment time will require close follow-up to see if any medical results remain the same since the old regimen was based upon outcome.



# What Do I Inspect?

- Written Policy and Procedures
  - The source calibration certificate
  - The decay calculation, signature of AMP?
- "35.433 Decay of strontium-90 sources for ophthalmic treatments.
- (a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.
- (b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433."



# What Do I Inspect?

- Procedure preparations (timer tested each day of use and decay calculations current?)
- Patient Calculations (clear, signed, dated)
- Patient identification documented?



# What Do I Inspect?

Adequate training?

"§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490, or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy...."



# What Do I Inspect?

- The source calibration certificate
- The decay calculation, signature of AMP?

"35.433 Decay of strontium-90 sources for ophthalmic treatments.

- (a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.
- (b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433."



# What Do I Inspect?

- Participating Staff training records (nurse, therapist, dosimetrist)
- Written Directive
- Patient Surveys (survey meter used identification, date signature?)



# What Do I Inspect?

- Survey meter calibration records
- " § 35.404 Surveys after source implant and removal.

Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.



# What Do I Inspect?

- Survey meter calibration records
- " § 35.404 Surveys after source implant and removal.
- .
- (c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404."
- Source location records, is source secure?





# What Do I Inspect?

" § 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406."

- Source bi-annual leak test records

- Annual Safety Training records

" § 35.410 Safety instruction"



# Conclusion

Treatment of Pterygium eye disorders via Surgery and Radiation offer the best results

As a High Dose Rate treatment Sr-90 Ophthalmic Applicators need appropriate written guidelines and need to be handled by appropriately trained professionals

NIST or Traceable Calibration Lab Calibration

Appropriate Decay (AMP)

Safe Handling Practices

Location Tracking

Regulatory guidelines must be followed



# Ophthalmic Applicators

THANK YOU !