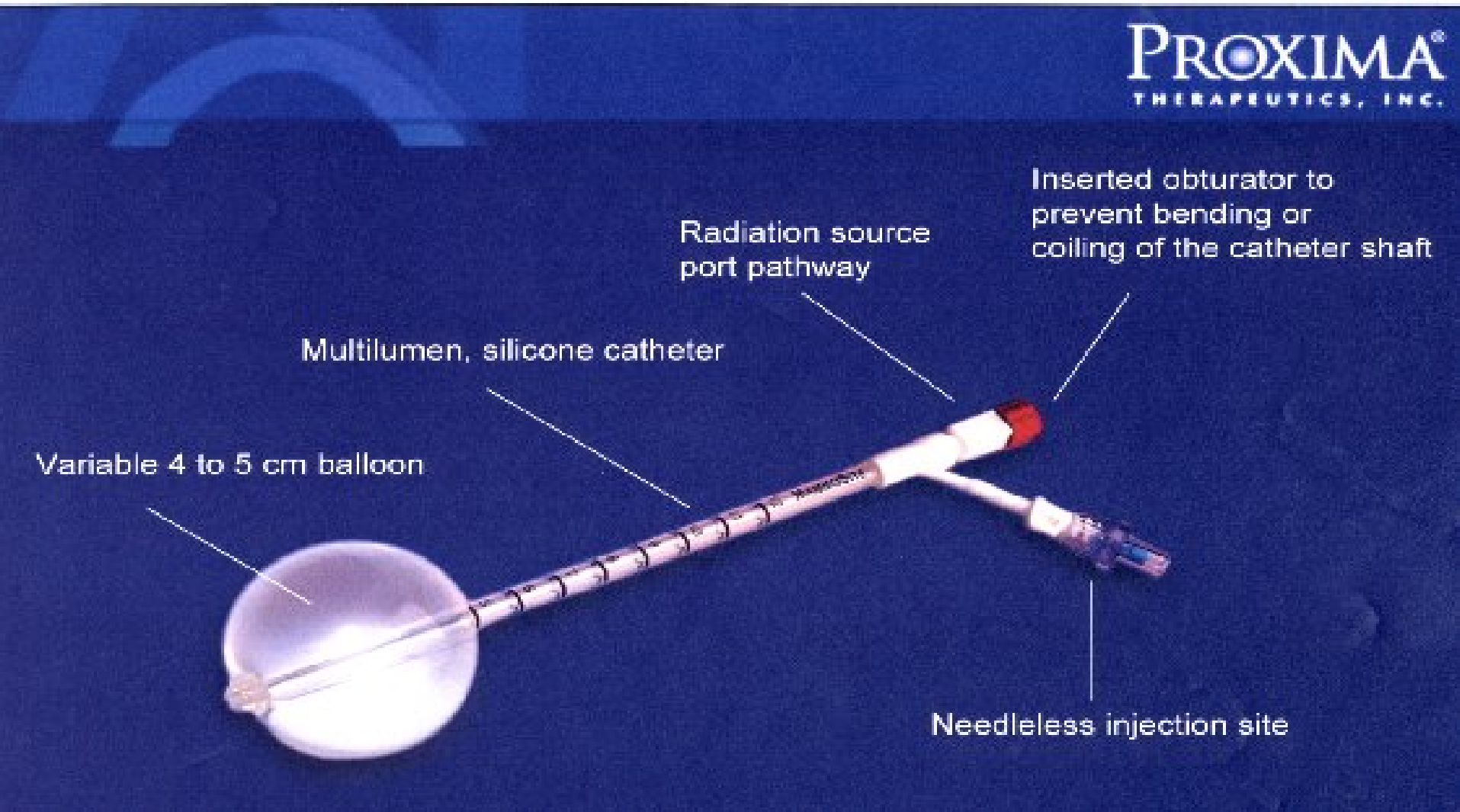
Introduction to MammoSite

Wayne Butler, PhD

Schiffler Cancer Center

Wheeling Hospital

The MammoSite device



Why MammoSite?

- Builds on the success of interstitial accelerated partial breast irradiation (APBI)
  - The entire treatment lasts only 5 days, not 7 weeks.
  - Patients can be treated before chemotherapy.
- Company hoped that women would prefer one large puncture to multi-needle implant
  - Cosmetic results may be better than conventional external beam therapy
- Less complicated than interstitial APBI
  - Apparent simplicity and short learning curve attractive to users

How it works

- Surgical cavity < 3 cm diameter
- Implanted balloon is pressurized to occupy about twice the original volume
- Tissue is incompressible but deformable
- Tissue as far away as 2 cm from the surgical margin may be pulled to within 1 cm of the balloon surface
- Deliver prescribed dose to r + 1 cm

The Catch

- MammoSite Radiation Therapy System is not cheap.
  - Implanted balloons are replaced at no cost if they can not be used.
- Some studies (Holland) show microscopic disease > 1 cm from tumor.
- FDA clearance in May of 2002, so there is no long term complications and survival data.
  - It has been debated that all PBI therapy should be on protocol.
- Conventional therapy probably has a slightly lower recurrence rate.
- The treatments are labor intensive
  - Physics staff devote many hours to this treatment.

APBI selection criteria used for spherical MammoSite treatments at the Schiffler Cancer Center

Parameter	Criterion
Tumor size	< 3 cm
Nodal status	N0, N1, H&E stain neg. (pan keratin pos. OK)
Metastatic status	M0
Surgical margins	≥ 1 mm
Extensive intraductal component	Negative
Lobular histology	No
DCIS alone	No
Age	Clinical judgment
Tumor location	Clinical judgment
Breast morphology	Clinical judgment
Skin spacing	≥ 7 mm
Balloon symmetry	L = W ± 3 mm
Air pocket volume	< 7 % of Treatment Volume
Off axis	≤ 3 mm

Breast Simulation Worksheet *(Part One)*

Patient Name _____ Patient ID_____

Date of implant _____ (FDA mandates 28 days max.)

Radiation Oncologist_____ Surgeon_____

Lot number _____ Implant length _____ Breast (R/L) _____

Exact volume of fluid in MammoSite _____ cc (35cc ≤ fill volume ≤ 70cc)
Note: fill with 5% non-ionic contrast solution.

Patient setup_____

Initial position _____mm Length retracted/extended _____mm

Source position _____mm (The value determined as the center)

Balloon length _____mm Balloon width _____mm (L = W ± 3mm)

Dosimetry information:

D_{90} _____cGy D_{100} _____cGy V_{100} _____ V_{150} _____ V_{200} _____

Max skin dose _____cGy Dose Homogeneity Index _____

Breast Simulation Worksheet
(Part Two)

Measurements from CT:

Balloon size	_____	**mm**	**(Measure diameter perpendicular to lumen.)**
Balloon to skin	_____	**mm**	**(Need at least 7mm)**
Balloon to rib	_____	**mm**	
Balloon to lung	_____	**mm**	
Balloon to heart	_____	**mm**	
Conformance	_____	**%**	**(Need at least 90% conformance)**
Off-axis distance	_____	**mm**	**(The symmetry requirement is ≤ 3 mm.)**

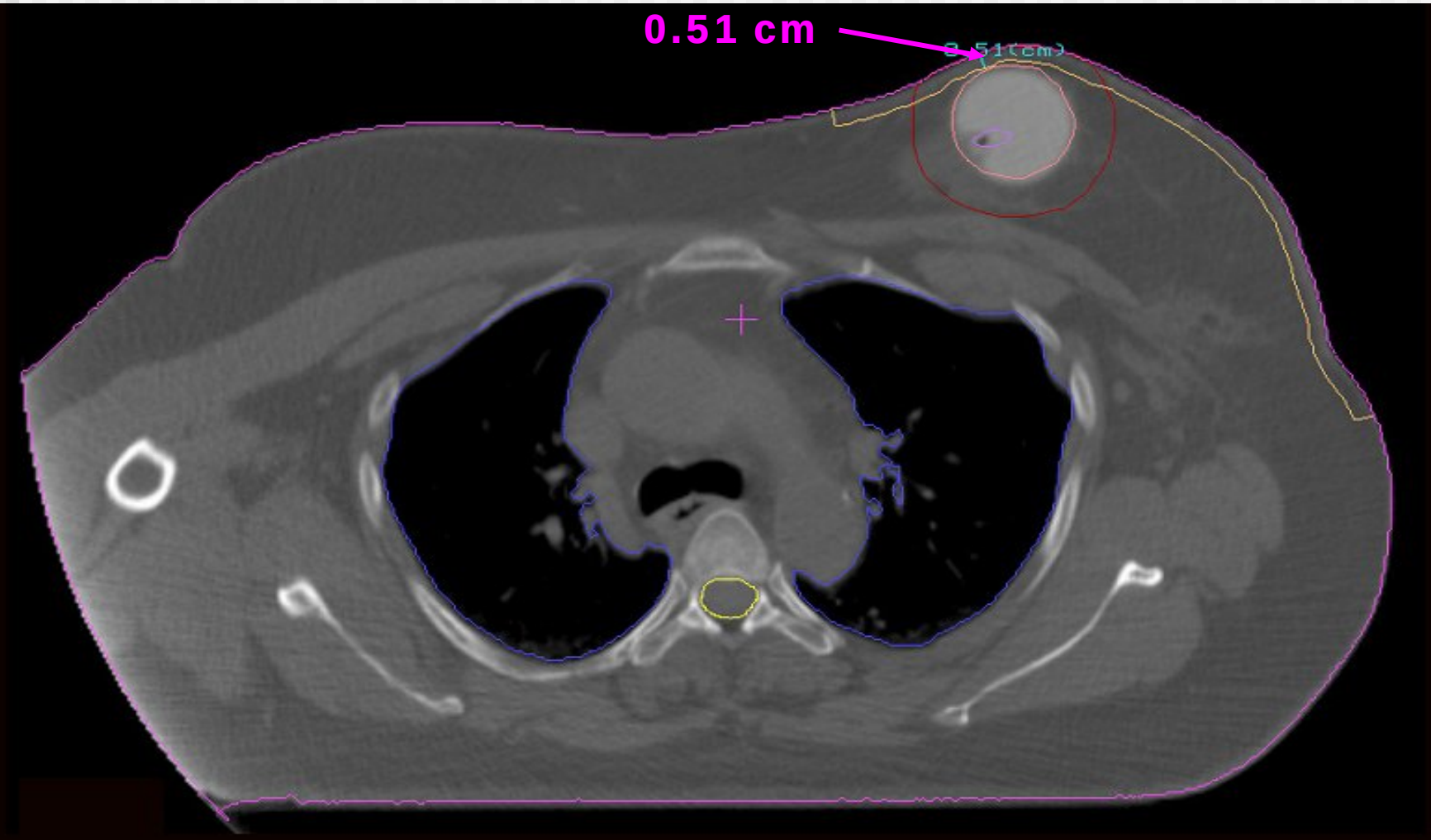
Calculated distances:

Prescription 1	_____	**mm**	**(Balloon radius + 1cm)**
Prescription 2	_____	**mm**	**– (Balloon radius + 1cm)**
Source to skin	_____	**mm**	**(Balloon radius + Balloon to skin)**
Source to rib	_____	**mm**	**– (Balloon radius + Balloon to rib)**
Source to lung	_____	**mm**	**– (Balloon radius + Balloon to lung)**
Source to heart	_____	**mm**	**– (Balloon radius + Balloon to heart)**
Calculation point	_____**100**_____	**mm**	

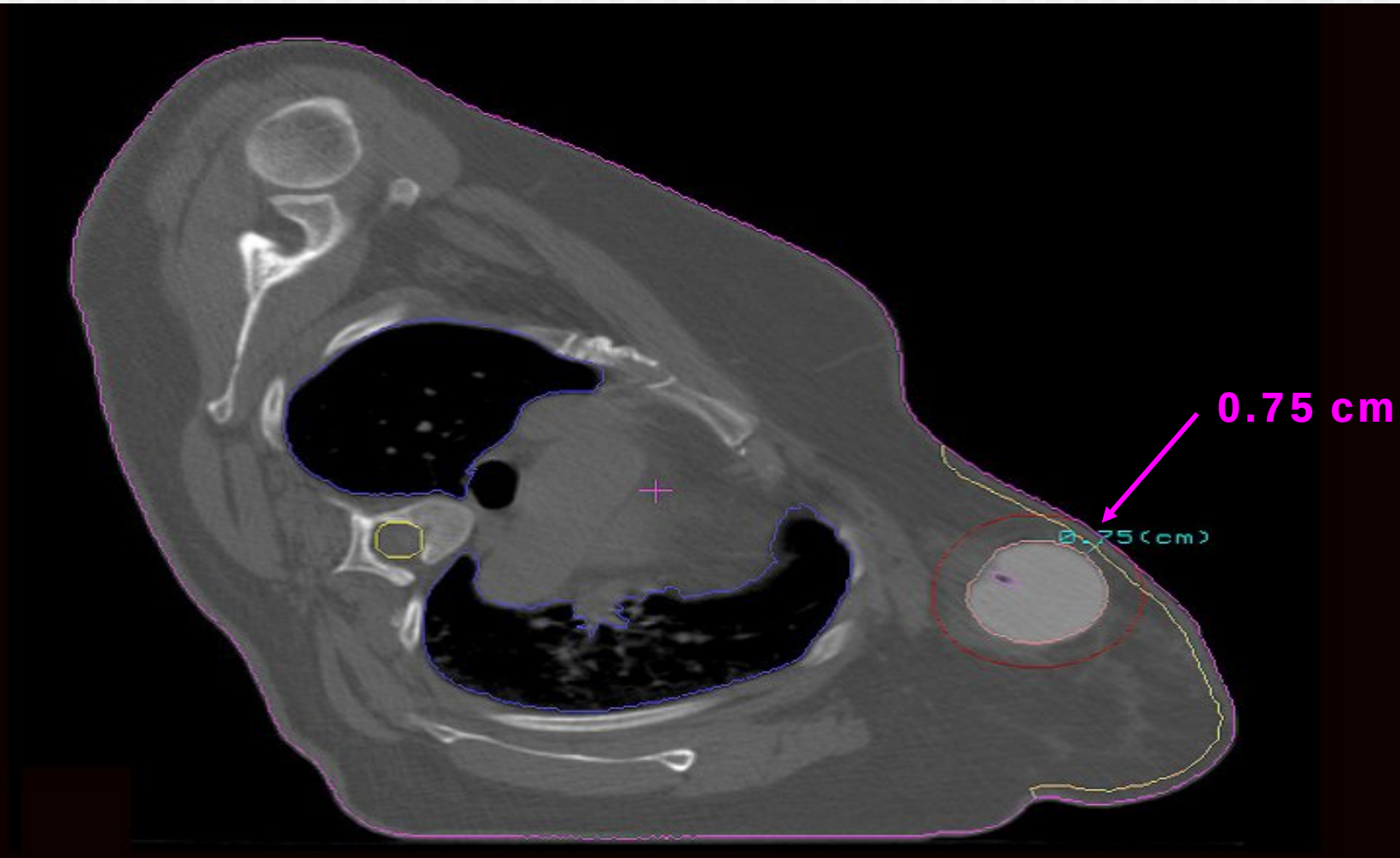
Evaluation of skin spacing

- Skin spacing is checked immediately after the scan.
- For skin spacing $\leq$ 7 mm, the patient is rolled and re-scanned.
- Rolling the patient onto the treatment breast often helps.
  - It may be impossible to keep everything in the field of view.
- An improvement of more than 2 mm can be achieved.
- Patients who are rolled will need to be re-simulated.
- The minimum balloon to skin distance is recorded.
- The balloon is removed if the skin spacing problem persists.
- Skin spacing less than 5 mm can cause severe reaction.

Skin spacing problem
(Patient supine)



Skin spacing solution
(Patient rolled)



A comparison of dosimetric data for the same patient in a supine versus a rolled position

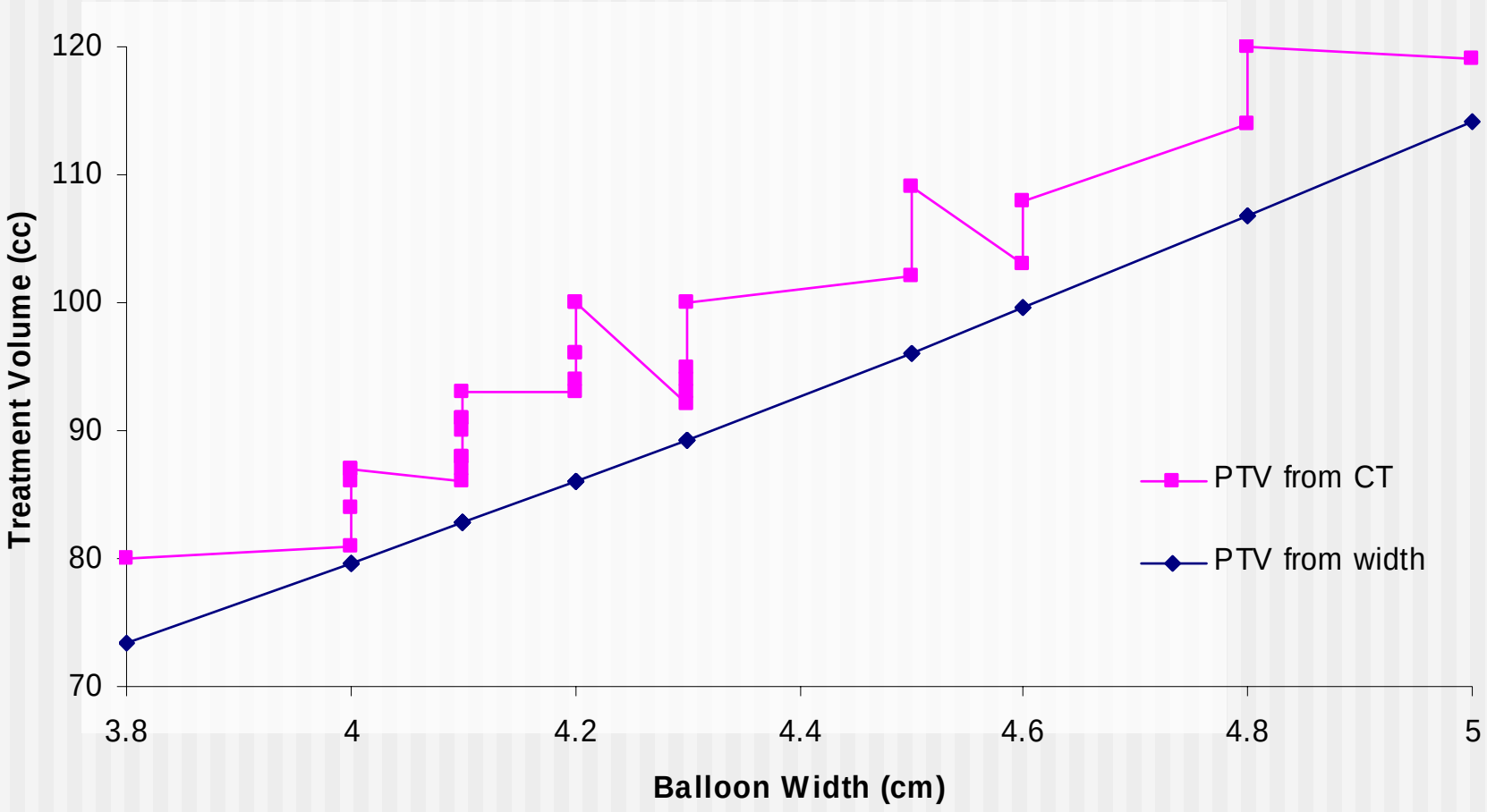
Position of Patient	Skin Gap from CT (mm)	PTV from CT (cm^3)	Dosimetric Data				
			D90 (cGy)	D100 (cGy)	V100 (%)	V150 (%)	V200 (%)
Supine	5.1	107.8	3269	1866	84	25	2
Rolled Lt.	7.5	114.0	3289	2270	84	22	1

Position of Patient	DHI	Max Skin Dose (cGy)	Max Lt. Lung Dose (cGy)	Max Rt. Lung Dose (cGy)	Max Heart Dose (cGy)
Supine	0.702	7105	2774	198	2086
Rolled Lt.	0.738	5472	1475	249	1765

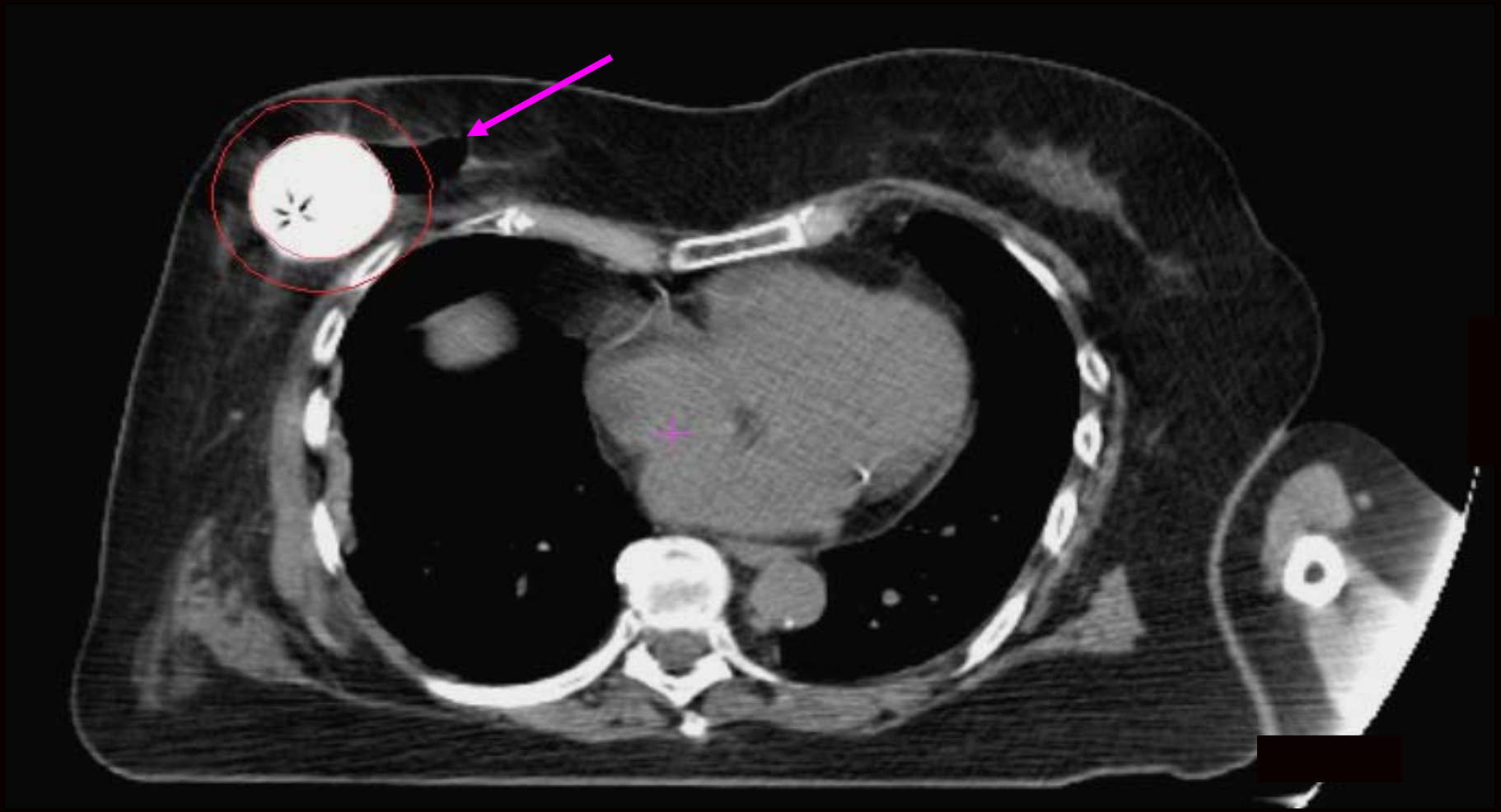
Examining the conformance

- Treatment planning software does not account for air pockets.
- The tissue conformance to the MammoSite should be > 90%.
- Contour all of the air pockets that are included in the PTV.
- The CT treatment volume = PTV – MammoSite volume.
- Verify that the volumes from CT contours are reasonable.
- CT treatment volumes should be > $4/3\ \pi\ (3r^2 + 3r + 1)$
- Air pocket volume / CT volume < 7%.
  - This allows for uncertainty in contours and interpolation.
  - The air will dissipate over time, about 1% per day.
  - Too much air just means wait and CT again.

Treatment volume vs. balloon width

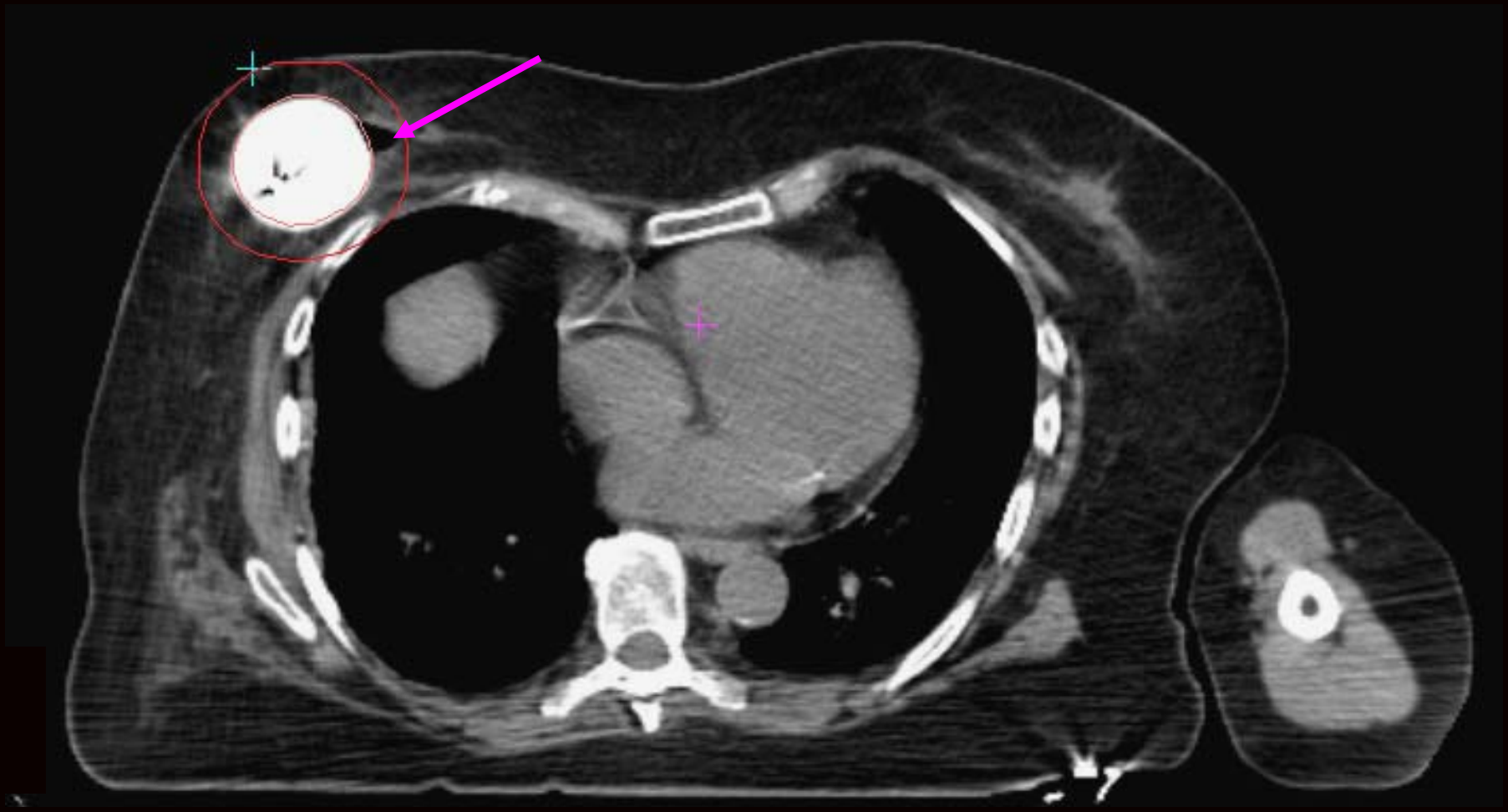


Air pocket problem



The initial conformity is 90.8%, with an 8 cc air pocket.

Problem solved by waiting 1 week

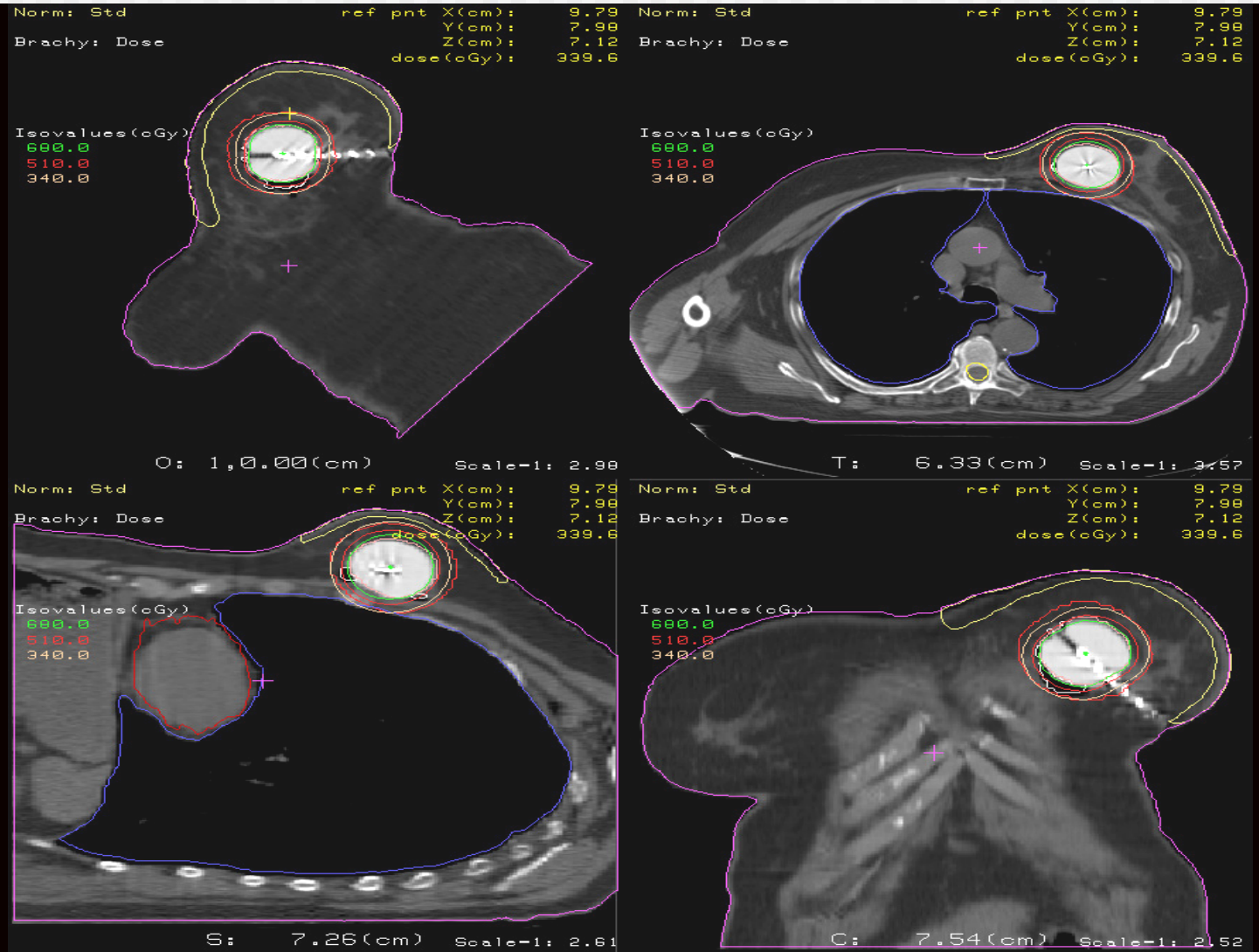


One week later, the conformity is 96.4%, with a 3 cc air pocket.

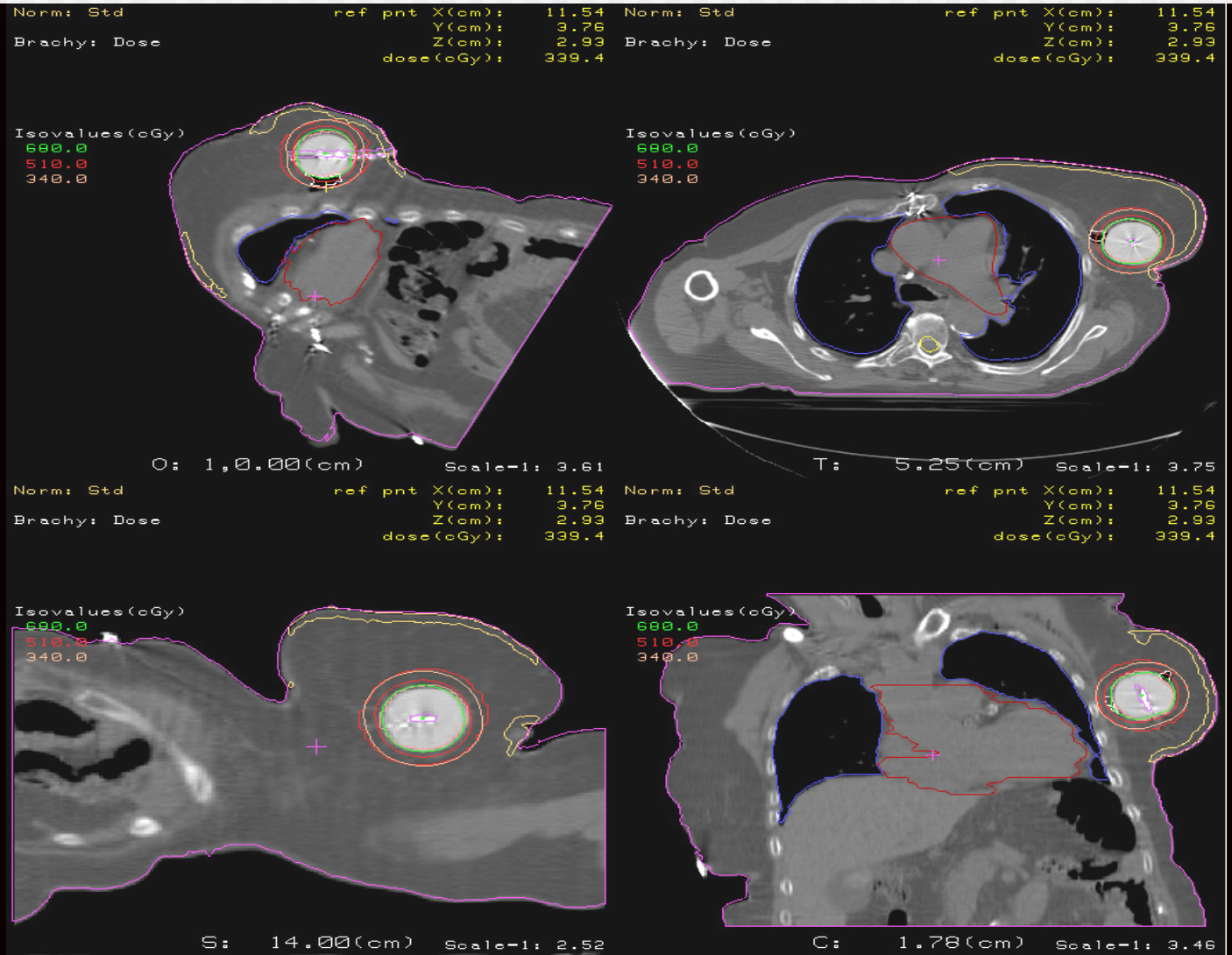
Evaluation of balloon symmetry

- MammoSites are not perfectly round spheres.
- Verify that L = W ± 3 mm on simulation films and CT.
- The smaller balloons tend to be less symmetrical.
  - They are often longer than they are wide.
  - Consider multi dwell?
- The balloon is often deformed when it is near the chest wall.
- The average width is critical to determining balloon size.
- The radius is defined as normal to the lumen.
- Prescription points are at r + 1 cm.

Poor symmetry



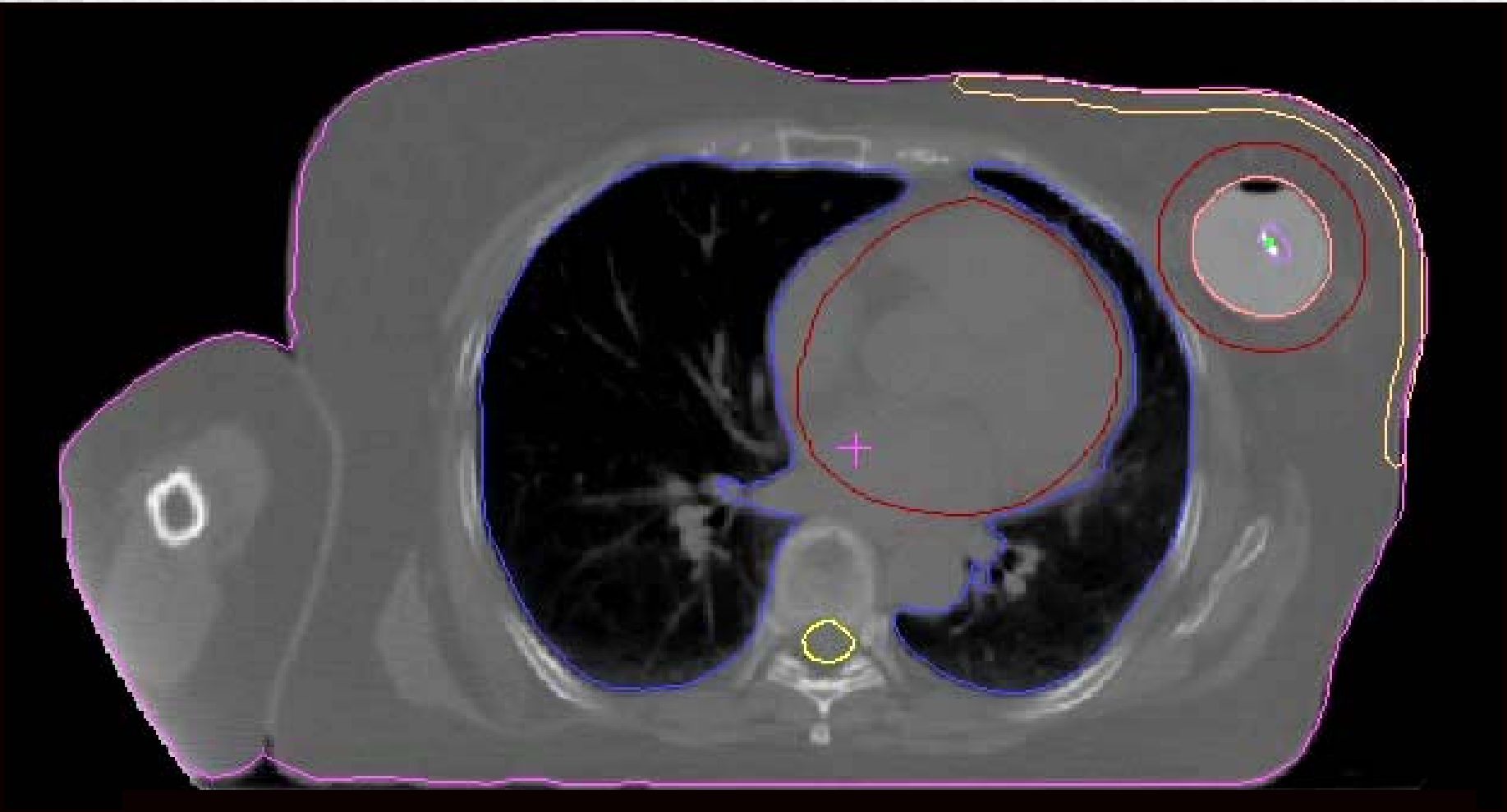
Good symmetry



Distance the source is off - axis

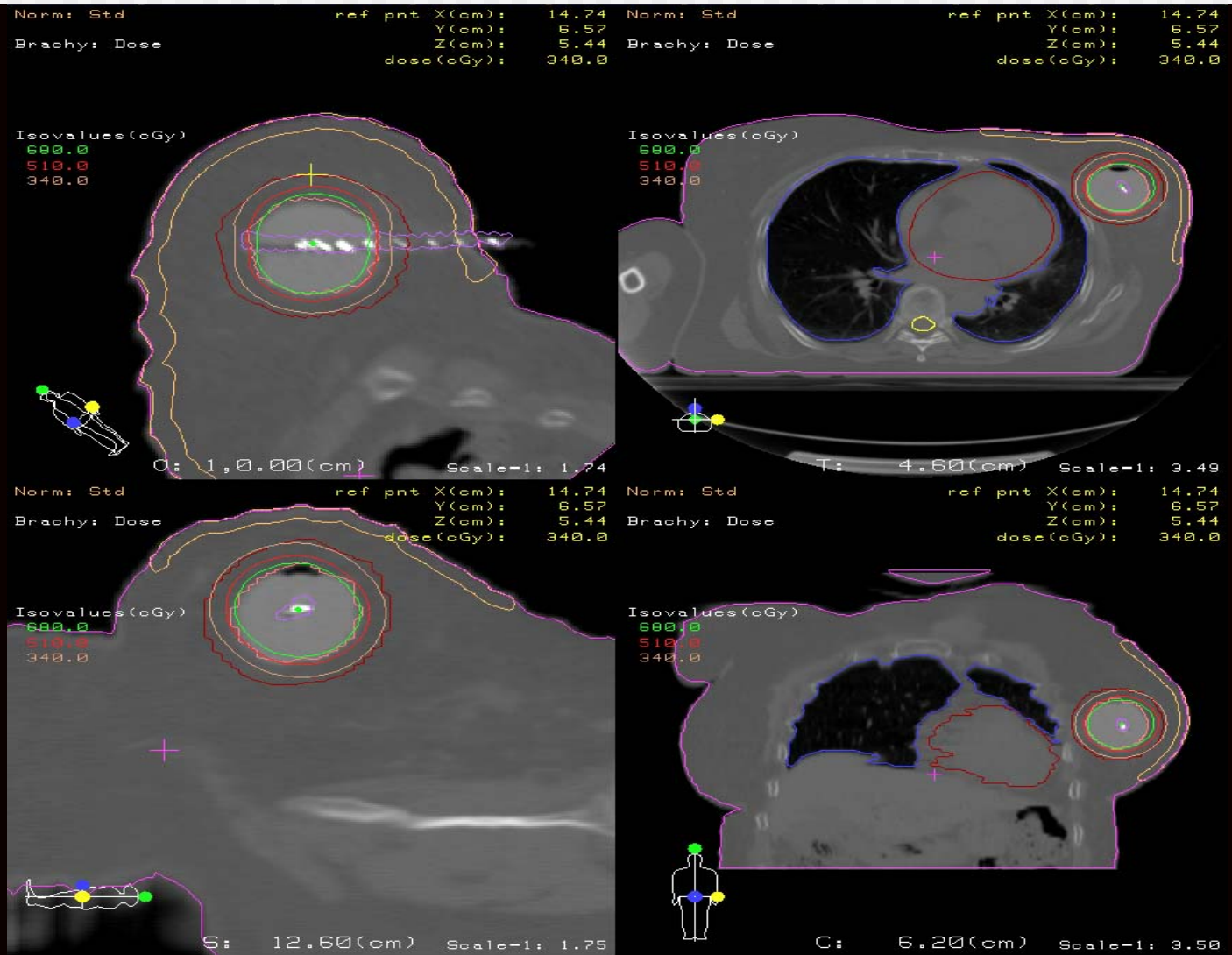
- Every 1 mm the source is off – axis affects the dose by 6% – 8%.
- The chest wall can cause a balloon to be very off – axis.
  - Deflate the balloon, rotate 90 degrees, and re-inflate.
  - This does not always work and often introduces air into the balloon.
- It is permissible to underdose the chest wall.
  - Therefore, prescribe to 1 cm in tissue and ignore chest wall dose.

Significant off-axis situation



The center is 2.5 mm off – axis.

Evaluating the situation



2-D planning using Plato and orthogonal films

- Setup the films with the MammoSite's center as origin.
- Digitize the balloon (marker points) and lumen (catheter).
- Digitize the source position and enter the length.
- Re-align the axis so the lumen is along the negative Z axis.
- Create prescription and dose QA points.
- Assign the dose (340 cGy) to the 4 prescription points.
- Determine the date and time for the treatment.
- Display the desired isodose curves.

Purpose of the 2-D plan

- Used to determine the dwell time for each treatment.
- The plan is updated with the date and time of each treated fraction.
- The source position can be adjusted by changing the length.
- Determine the max dose to various critical structures.
- Examine the effects of an off - axis source.
- Observe the consequences of any asymmetry.
- Print isodose curves and the plan report.
- Export the plan directly to the treatment console.

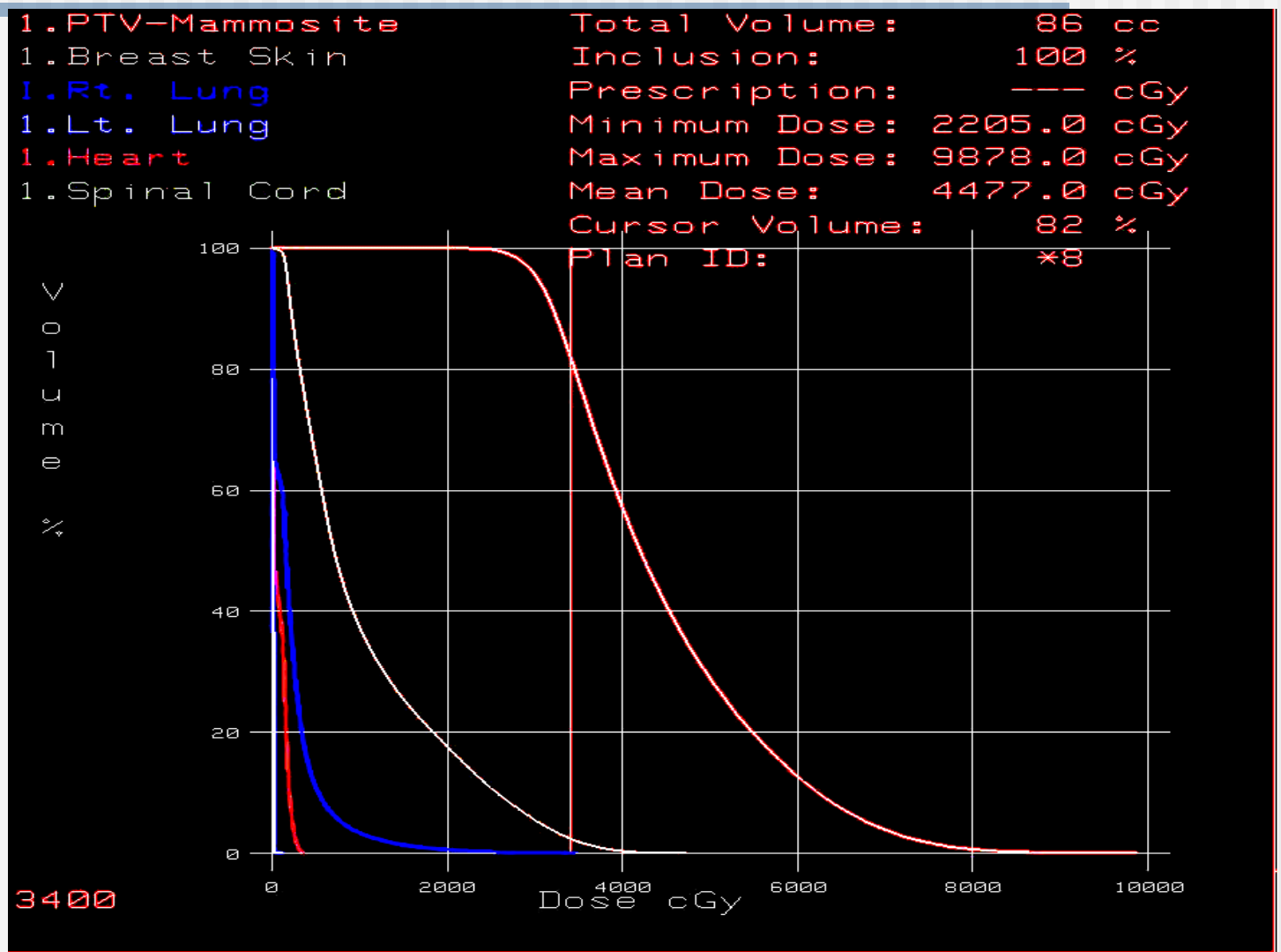
3-D CT planning using Xio brachytherapy

- Create an oblique view that captures the dummy seed wire.
- Place the source on the dummy seed in the oblique view.
- Pick “treatment” and enter the specific date and time.
- Choose “Dispdose” and “Set Treatment Duration”.
  - The duration needs to be adjusted into: Day / Hour / Minute.
- Create isodose curves and dose volume histograms.

Purpose of the 3-D plan

- Used to obtain a 3-D visualization of the treatment.
- See the effects of balloon irregularities and anisotropy.
- The plan is created for the initial treatment and a composite.
- The DVH is generated for the single treatment and composite.
- Dosimetric data and the doses to critical structures are obtained.
  - Dose Homogeneity Index: DHI = 1 - (V150 / V100)

Sample Dose Volume Histogram



Quality Assurance

Twice daily QA, done before each treatment:

- Reproduce the patient setup as well as possible.
- Take orthogonal simulation films using the dummy source.
- Check that the source position is still the balloon's center.
- If the source is more than 1 mm off, adjust the system.
- Check the width and length of the balloon.
- If any dimension changes by 2 mm, verify the fill volume.

Q.A. equation using Proxima tables

Do not proceed if variation > 5%

$$\text{Total Dwell Time(min)} = \frac{\text{Dose(cGy)}}{\text{Dose Rate}\left(\frac{\text{cGy}}{\text{min}\cdot\text{Ci}}\right) * \text{Strength(Ci)}}$$

$$\underline{\qquad\qquad\qquad}\text{(min)} = \frac{\underline{\qquad\qquad}\text{(cGy)}}{\underline{\qquad\qquad}\left(\frac{\text{cGy}}{\text{min}\cdot\text{Ci}}\right) * \underline{\qquad\qquad}\text{(Ci)}}$$

$$\text{Variation} = 1 - \frac{\text{Manual Calc Value}}{\text{Computer Value}} = 1 - \frac{\underline{\qquad\qquad}\text{(min)}}{\underline{\qquad\qquad}\text{(min)}} = \underline{\qquad\qquad\qquad}\ \%$$

Physical and dosimetric characteristics for the variably inflated MammoSite balloons (Proxima tables)

4 – 5 cm MammoSite				5 – 6 cm MammoSite			
Nominal fill volume (cm^3)	Width (cm)	Length (cm)	Dose Rate * (cGy/min/Ci) @ 1 cm	Nominal fill volume (cm^3)	Width (cm)	Length (cm)	Dose Rate * (cGy/min/Ci) @ 1 cm
34	4.00	4.00	8.43	70	4.87	5.11	6.37
36	4.05	4.05	8.20	75	4.96	5.17	6.21
38	4.15	4.10	7.98	80	5.06	5.22	6.03
40	4.20	4.10	7.79	85	5.15	5.28	5.88
42	4.30	4.15	7.58	90	5.24	5.33	5.74
44	4.35	4.20	7.44	95	5.34	5.39	5.58
46	4.45	4.25	7.27	100	5.43	5.45	5.45
48	4.50	4.30	7.10	105	5.52	5.50	5.32
50	4.55	4.30	6.97	110	5.62	5.56	5.18
52	4.65	4.35	6.83	115	5.71	5.61	5.06
54	4.70	4.35	6.70	120	5.80	5.67	4.94
56	4.75	4.40	6.58	125	5.90	5.72	4.82
58	4.85	4.40	6.44				
60	4.90	4.45	6.35				
62	4.95	4.50	6.26				
64	5.00	4.55	6.15				
66	5.05	4.60	6.05				
68	5.10	4.60	5.97				
70	5.15	4.65	5.89				

* Dose Rate calculation is at 1 cm outside of the balloon surface.

TG-43 based equation:

Do not proceed if variation > 5%

$$\text{Dose@10cm(cGy)} = 2.75 \cdot 10^{-6} \left(\frac{\text{cGy}}{\text{U} \cdot \text{s}} \right) * \text{Strength(U)} * \text{Time(s)}$$

$$\underline{\qquad\qquad}(\text{cGy}) = 2.75 \cdot 10^{-6} \left(\frac{\text{cGy}}{\text{U} \cdot \text{s}} \right) * \underline{\qquad\qquad}(\text{U}) * \underline{\qquad\qquad}(\text{s})$$

$$\textbf{Variation} = 1 - \frac{\textbf{Manual Calc Value}}{\textbf{Computer Value}} = 1 - \frac{\underline{\qquad\qquad}(\textbf{cGy})}{\underline{\qquad\qquad}(\textbf{cGy})} = \underline{\qquad\qquad\qquad}\ \%$$

Pretreatment procedure

- Hook up the catheter to minimize source transit exposure of the contra lateral breast.
  - Try to straighten and level the catheter by positioning the unit.

Treatment procedure

- Treatments are 340 cGy BID for 5 consecutive days.
- At least six hours must elapse between treatments.
- Remove the catheter and connector, and replace the obturator.
- Complete the post-treatment radiation survey.
- Have a nurse assist with the bandaging.
- Make sure the patient knows when to return.

Treatment situations

- The patient might request assistance during the treatment.
  - Treatment can be interrupted and resumed with a button push.
- The center position can sometimes change due to patient's daily motion.
  - The connector can be tightened or loosened for small adjustments.
  - Adjust the dummy seed to find the new center for shifts $\geq$ 1 mm.
  - Only the 2-D length is corrected since the source is recentered.
- The dimensions of the balloon might change by $\geq$ 2 mm.
  - Look for the same change on both of the orthogonal films.
  - If the balloon seems to be shrinking then check for a leak.
  - Consider all the options when dealing with a leaking balloon.

Removal of the MammoSite

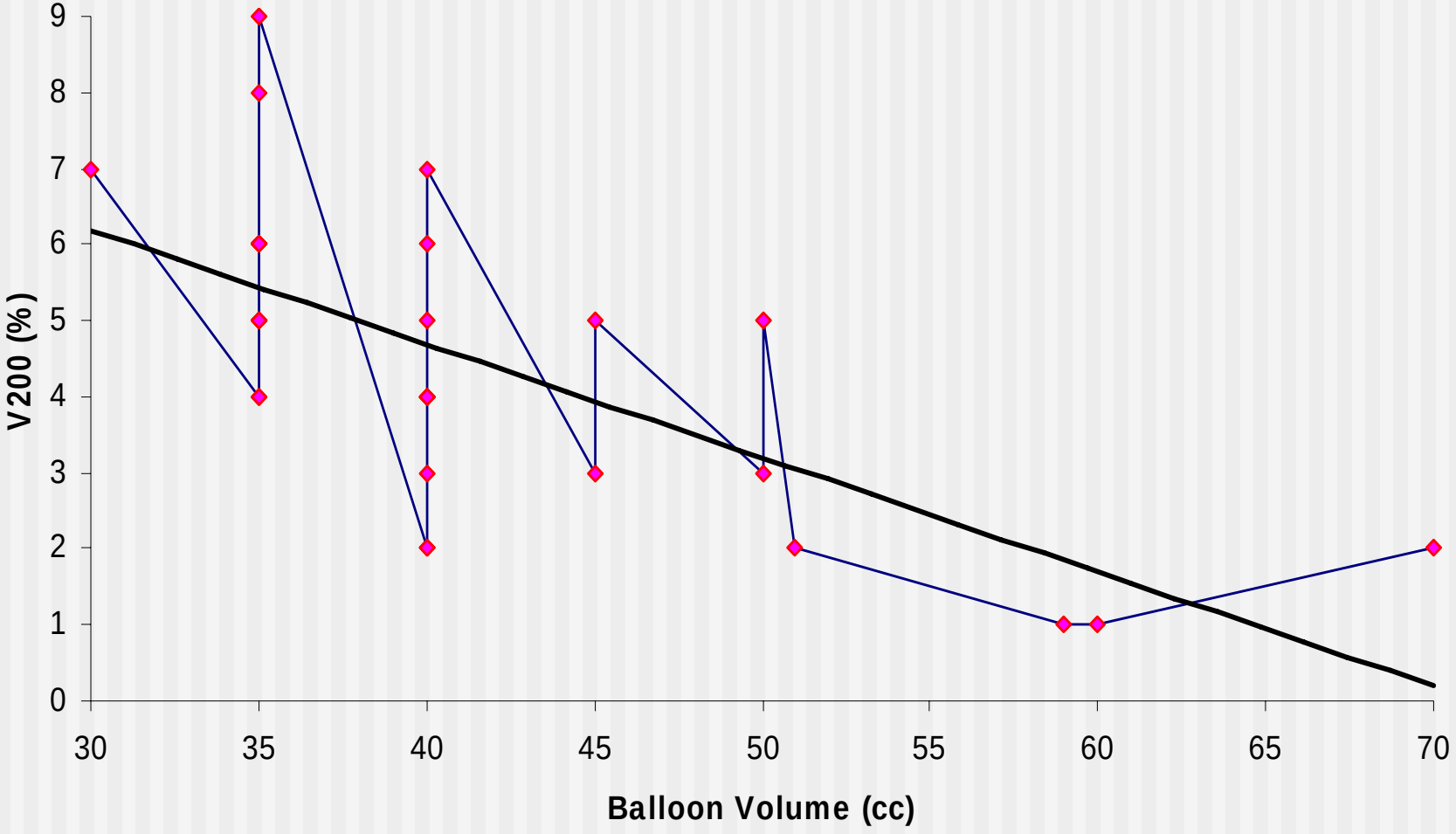
- Patients are given Ativan to be taken 1 hour before the last treatment.
- Roxanol is orally administered just prior to the last treatment.
- Removal occurs after the 10th treatment, in the treatment room.
- The balloon is deflated, and the fill volume is verified.
- The device is pulled out with a swift motion.
- Most patients consider the removal mildly unpleasant.
- Patients are given a follow up schedule before they leave.

Dosimetric data for the MammoSite breast brachytherapy applicator

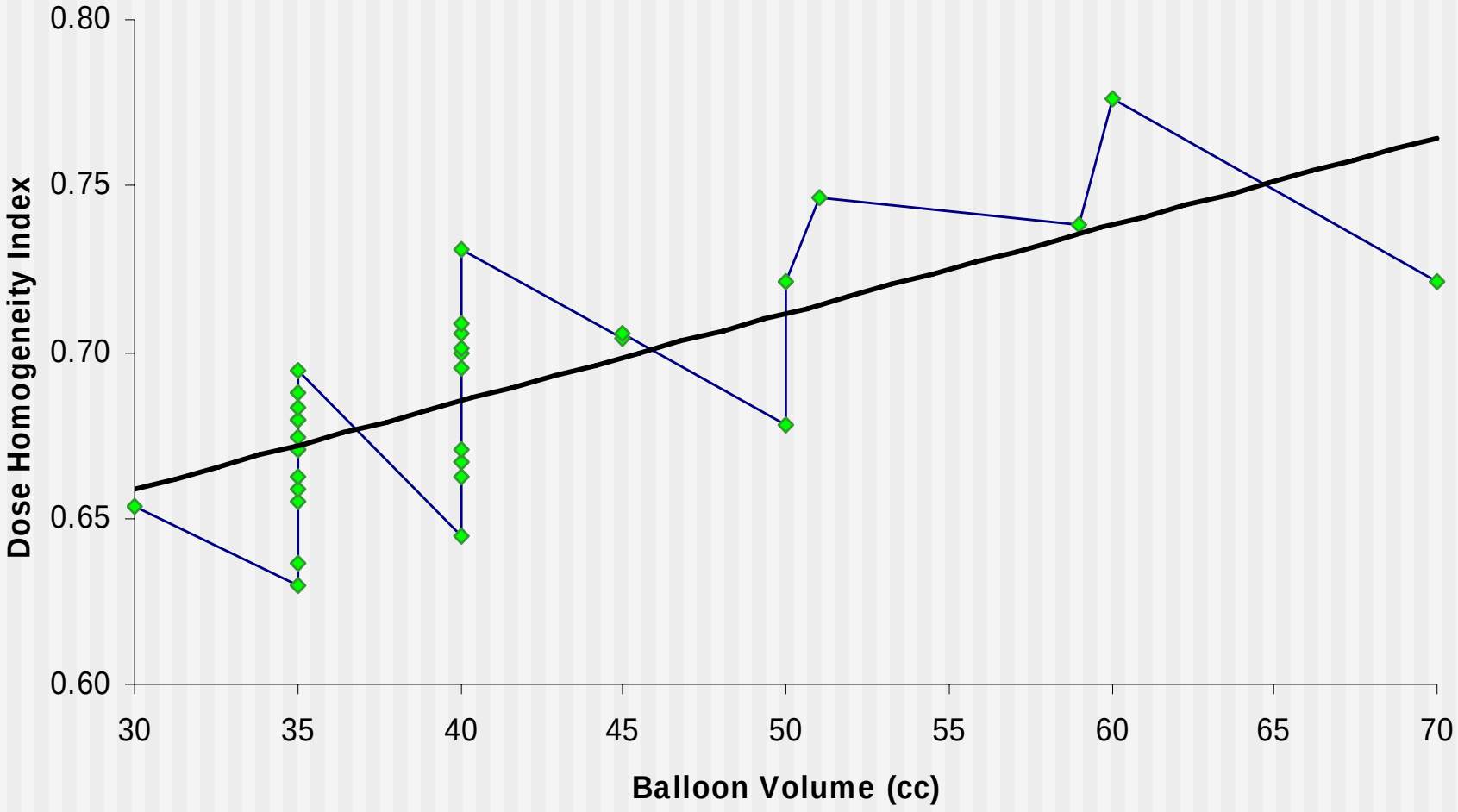
		Balloon Volume (cm^3)	Balloon width (mm)	PTV from width (cm^3)	PTV from CT (cm^3)	Center Position (mm)	Skin Distance (mm)	Tissue Conform-ance (%)
Edmundson	Mean	58.3	47.4		112.1		8.5	
	(SD)	12.7	3.7		15.7		3.0	
Schiffler CC	Mean	41.7	42.7	88.6	95.5	989.9	13.0	97.8
	(SD)	9.4	0.3	9.8	10.8	1.5	7.0	2.1

		Off-axis distance (mm)	D_{90} (cGy)	D_{100} (cGy)	V_{100} (%)	V_{150} (%)	V_{200} (%)	DHI
Edmundson	Mean				84.9	19.8	0.5	0.77
	(SD)				12.7	2.3	0.5	0.04
Schiffler CC	Mean	.94	3190.5	2137.6	81.1	25.4	4.5	.69
	(SD)	.57	137.8	143.7	5.1	3.7	2.0	.03

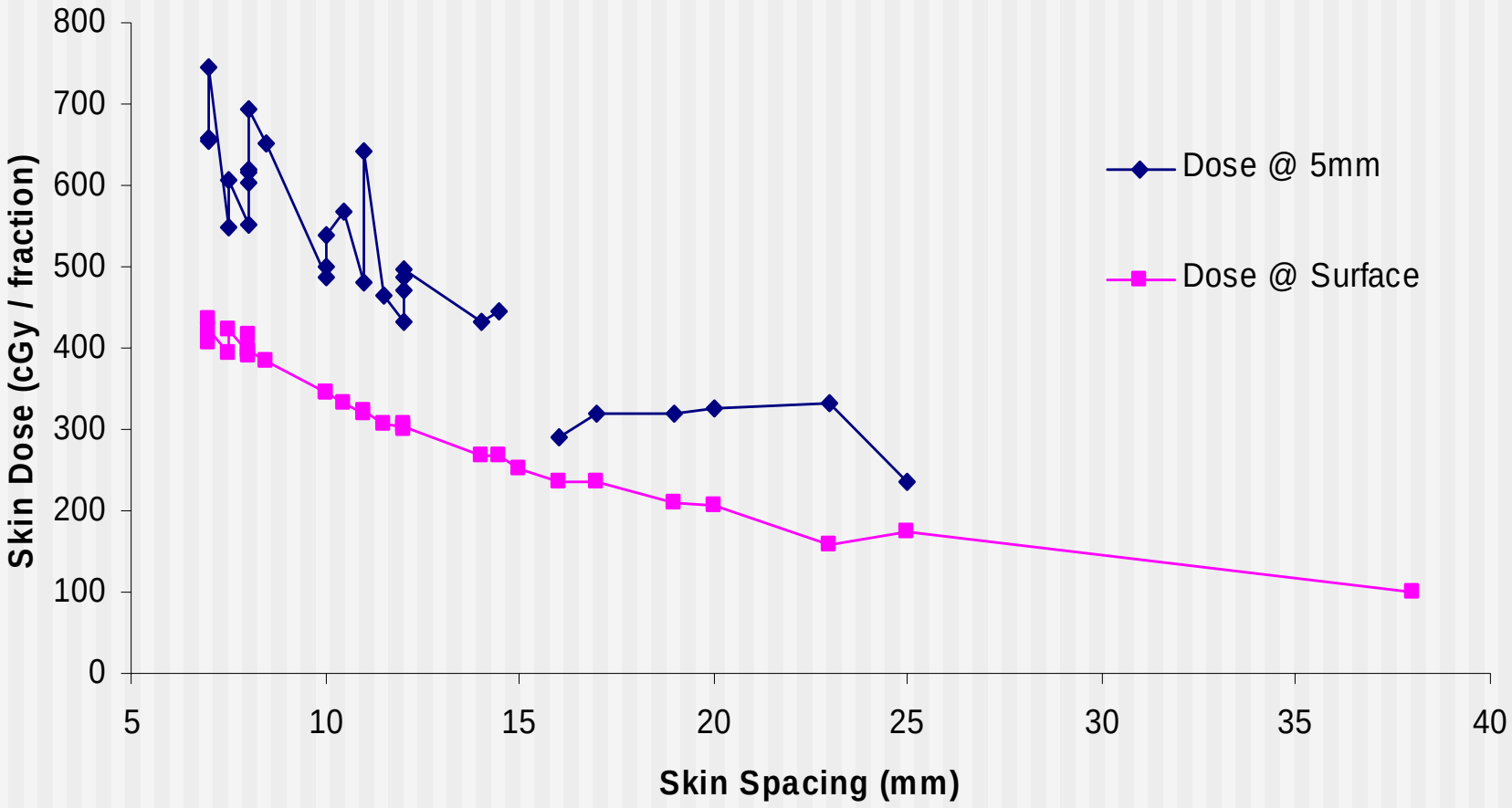
Balloon volume vs. V_{200}



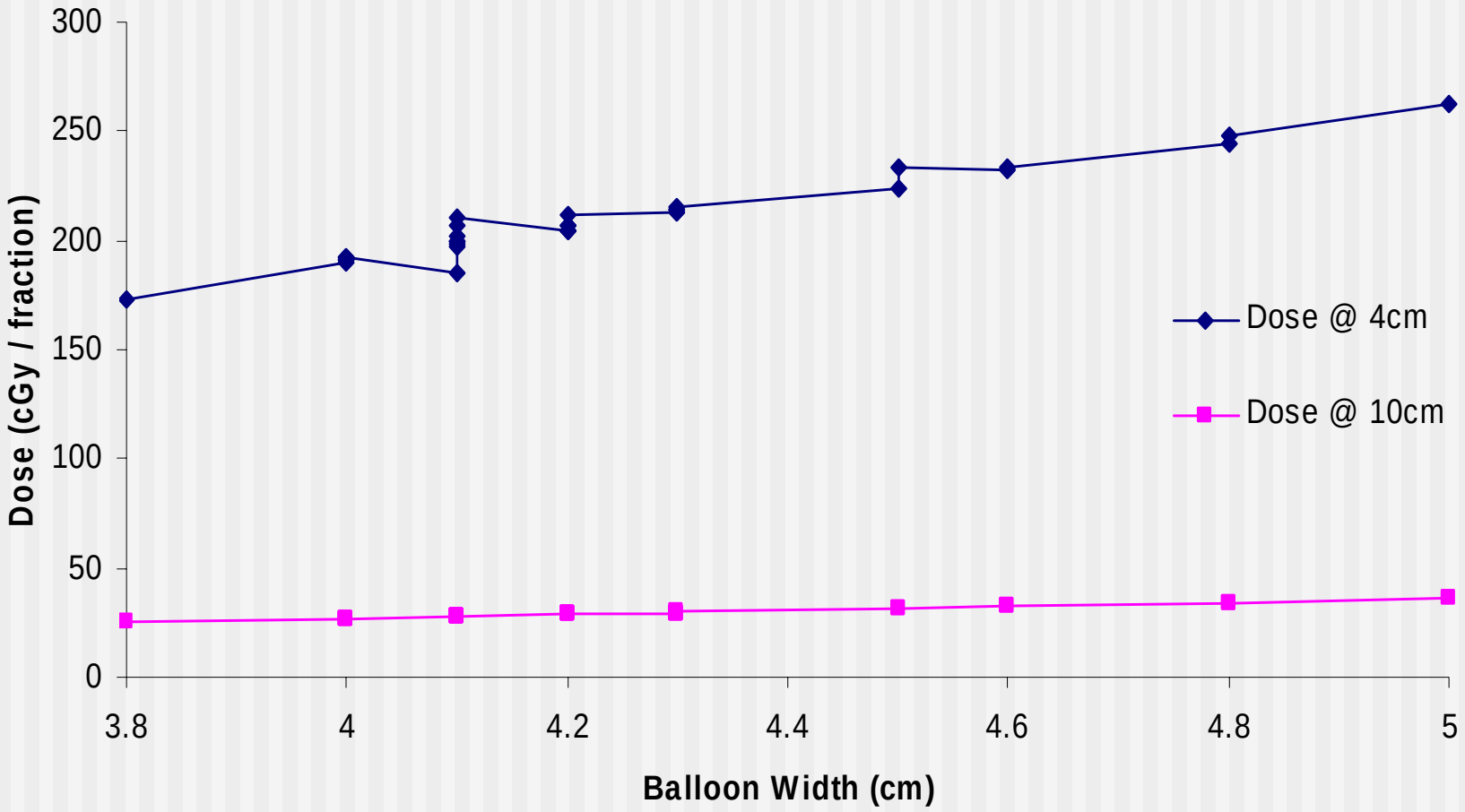
Balloon volume vs. DHI



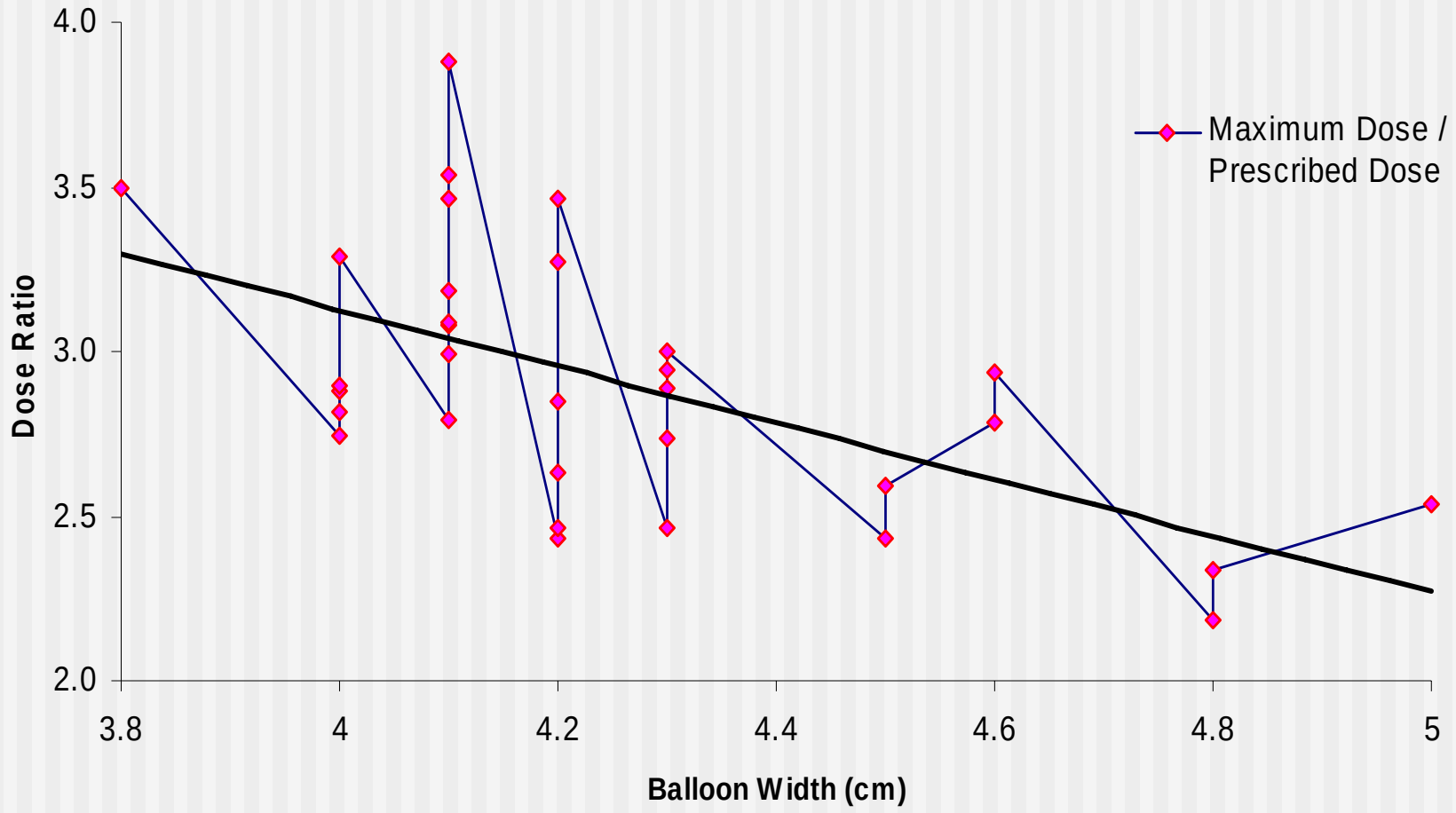
Skin spacing vs. skin dose



Balloon width vs. dose at a distance



Balloon width vs. maximum dose/prescribed dose ratio



Conclusion

- Because tissue at risk is forced to conform to the MammoSite balloon, coverage is more consistent and uniform than with interstitial Bx
- MammoSite is limited by cavity size, conformance, and skin spacing constraints
- There is no long-term follow-up to MammoSite
- Partial breast 3DCRT can provide more complete coverage of the PTV but at the cost of greater normal tissue dose