

TECHNIQUE FOR QUANTIFYING BALLOON SHAPE AND RESULTS OF A CONSISTENCY EVALUATION

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ABSTRACT

Purpose: There are many situations in which one would like to measure the shape of balloons used in accelerated partial breast irradiation (APBI), e.g., for comparing actual to design specification, for determining variability, for evaluating consistency over time, and for qualifying new vendors. Such balloons come in several sizes and shapes, including ones which are approximately spherical and ellipsoidal. Traditional quantitative inspections tend to be limited to diameter and length. Largely due to the complexity of shape, visually driven inspections, even those using images acquired by photographs or inspection devices, are typically limited to being essentially qualitative. When quantitative it is typically so in only a limited sense; for example, determining the diameter at one or several locations. Yet there is a great deal more information available in principle. Thus a means of acquiring image data and processing it to allow full characterization of balloon shapes is highly desirable.

Materials and Methods: A digital camera and the balloon under test are arranged in a dedicated fixture at a fixed distance and orientation. Lighting of the balloon is set so that the image stands out clearly from the background, allowing image processing software (NIH ImageJ) to easily identify the balloon circumference and create an image data file with only the edge as non-zero elements. Further processing in a custom LabVIEW program identifies the set of edge points and determines their locations in the image in x-y coordinates, interpolates the angular values at increments of one degree, and creates a table and plot of radial distance from image center as a function of angle relative to image center. This data completely specifies the balloon shape and allows direct numerical comparison of different balloons, calculation of average shapes and standard deviations as a function of angle, etc.

Results: Variation in balloon shape was measured for a single balloon inflated/deflated 5 times, for 5 different balloons inflated to the same volume, and for 4 rotations of the same balloon. Overall shape reproducibility in terms of standard deviation averages about 1%, or about 0.4 mm in the former two cases, and approximately 2% in the latter case.

Conclusions: The technique described provides detailed quantitative evaluation of the shape of Xoft Axxent® balloons used in APBI. It will be used to qualify a new manufacturing process at the current vendor and to qualify first articles produced by a new vendor. Presenting a predictably uniform shape is important dosimetrically in any brachytherapy treatment but especially so in uses such as intra-operative radiation therapy (IORT) where CT scan data is not readily available, and the nominal balloon shape must be assumed in planning the treatment.

BACKGROUND

- Over the past two years, the Axxent® Electronic Brachytherapy (eBx) System has been used to deliver accelerated partial breast irradiation (APBI) using an inflated balloon placed into the patient's resection cavity one to two weeks post-lumpectomy.
- The balloon applicator is a sterile, disposable, single use device that functions as a guide for the x-ray source. An integral drain was built into the balloon applicator for seroma management, which potentially improves dosimetry and reduces the infection rate. The radiolucent balloon wall improves visibility on planar film and in CT images. See Figure 1.
- Water-filled balloon applicators for the Axxent® eBx System have been FDA-cleared for breast APBI in five different sizes: 3-4 cm, 4-5 cm and 5-6 cm spherical shapes plus 5x7 cm and 6x7 cm ellipsoidal shapes.
- When used with the Axxent® X-ray Source operating at 50 kVp and 0.30 mA beam current, dose rates at 1 cm into tissue surrounding the balloon range from approximately 0.2 Gy per minute for the largest balloon to 1 Gy per minute for the smallest.
- When the prescription surface is 0.5 cm from the balloon, the dose rates increase by about 50% to 0.3 Gy per minute for the largest balloon and 1.5 Gy per minute for the smallest.
- Xoft has submitted an application to the U.S. FDA to allow use of these balloons in locations other than the breast, for example in intra-operative radiation therapy (IORT).

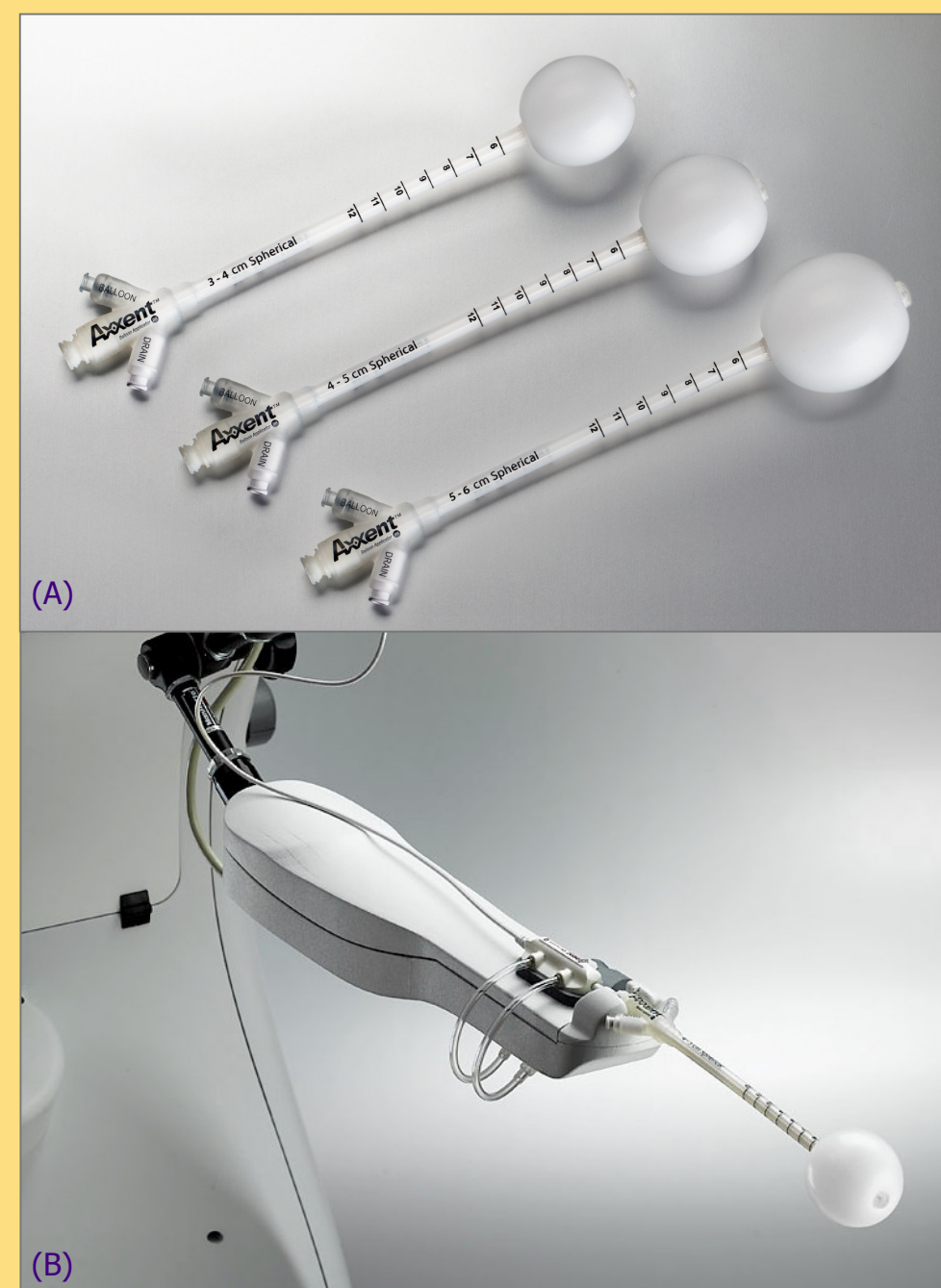


Figure 1 (A) The 3-4 cm, 4-5 cm, 5-6 cm spherical balloon applicators (B) Axxent® Controller arm showing the inflated balloon applicator

The Axxent® eBx System

- The Axxent® controller (Figure 2) provides power to the X-ray source and allows the X-ray source to be translated. The translation or pullback movement of the X-ray source within the balloon is designed to provide a predictable dose of radiation in the tissue surrounding the balloon.
- The Axxent® system can be used as an alternative to HDR sources such as Ir-192. Unique attributes of the Axxent® eBx System include:
 - No radioisotope regulatory, handling and safety issues.
 - Lower shielding requirements, which brings HDR treatment "out of the bunker."
 - High dose rate and unique dose sculpting capabilities.
 - Staff can be in the room with the patient during treatment
- The Axxent® eBx System is a self-contained unit that can be wheeled from one procedure room to the next.



Figure 2. Axxent® System Controller

INTRODUCTION

- Since brachytherapy dose depends strongly on geometry (distance from source to tissue), manufacturing tolerances are both stringent and challenging. For example, the central lumen is required to be centered to within approximately 1 mm to minimize asymmetric dose delivery.
- While parameters such as lumen centering, length and diameter are relatively straightforward to measure, the detailed shape of the balloon is a less easy thing to define and determine. Yet it is obvious that having a reproducible shape, either from one balloon to the next or when re-inflating a given balloon, is highly desirable.
- A new technique has been developed which enables complete characterization of a projection of the balloon shape to arbitrary precision.
 - It uses digital photography and a unique image processing technique to obtain spatial coordinates of the balloon edges.
 - Typically the outer edge of a slice through the longitudinal center would be characterized in x-y space, in 1 degree steps, with a precision of better than ± 0.1 mm.

METHODS

Image Acquisition

- The balloon under test is inflated with water to a fixed volume and inserted into a test setup that locates it reproducibly with respect to a mounted digital camera (Figure 3). It is enclosed in a box to control the lighting with an appropriate dark backdrop. The camera (EOS Rebel XT, lens EF-S18-55MM) is manually focused at an f-stop of 3.5, with typical exposure time of 2 seconds in b/w mode with zoom set at the extreme out position. Lighting intensity and direction are both important for obtaining images that yield reproducible results.

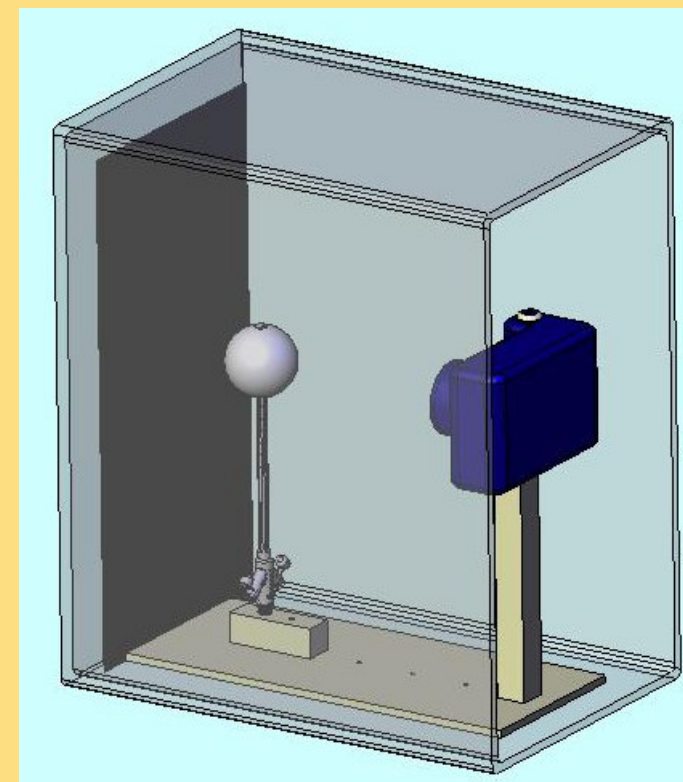


Figure 3. Layout of the apparatus used to acquire the photographic images of the balloons. Camera and balloons are mounted in fixed locations within an enclosure to ensure reproducibility of image size and illumination.

- Images are downloaded to a computer, where they are opened in NIH ImageJ, a freely available software package. ImageJ functions are used to center and crop to a standard size, eliminate the balloon shaft, find the balloon edges, and finally "threshold" the image. Edges are identified by sharp changes in intensity. In image thresholding, all pixels values below a certain number are set to zero, while all above that number are set to a fixed value. Both of these functions are standard features available in ImageJ. Figure 4 shows the cropped image while figure 5 shows it after edges are identified and thresholded. The images here are 700 pixels on a side. A photograph of a ruler was taken in the same position in the apparatus to establish the number of pixels per cm.



Figure 4. Cropped image of balloon

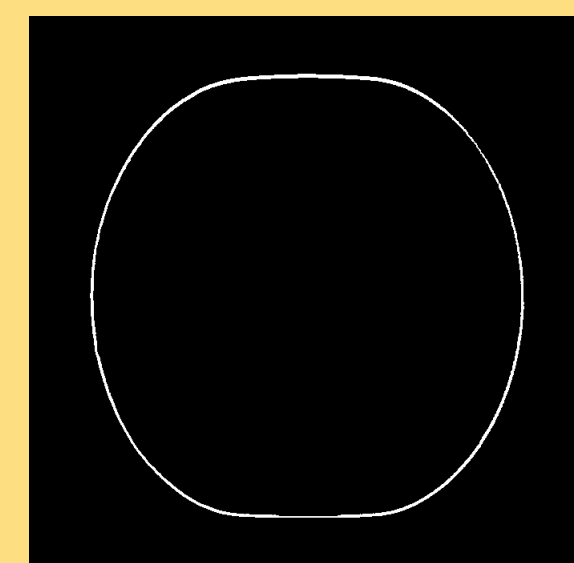


Figure 5. Thresholded image of balloon outline.

METHODS

Analysis

- A custom LabVIEW program further processes the thresholded image. A specially written routine identifies sets of contiguous non-zero pixels and stores them in linear arrays which record their positions in the 2-D image array. In this case there is only one such set per image. It then plots a "shape graph" of the distance from image center as a function of the angle about the center of each identified point. If the balloon was a perfect circle, the plot would be a horizontal line. The shape graph of a perfect ellipse with a long axis to short axis ratio of 1.20 is shown in Figure 6.

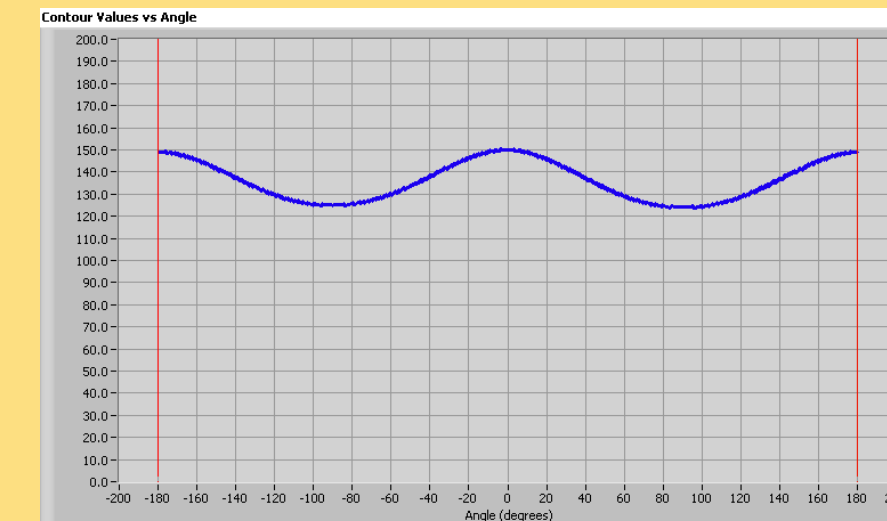


Figure 6. Shape graph of a perfect ellipse

- Figure 7 shows the shape graph of an actual balloon. The vertical scale is radius in cm, and the horizontal scale is angle in degrees. To reduce noise from the edge detection and thresholding processes, the raw data is smoothed by averaging 5 adjacent points. To facilitate comparisons between balloons, the data is then resampled to provide a radius value at each integer degree.

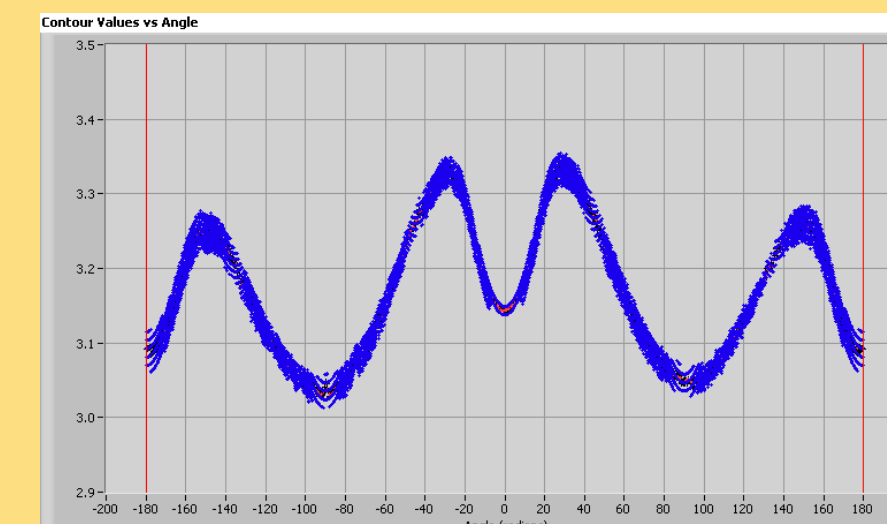


Figure 7. Shape graph of elliptical balloon

- Figure 8 shows the data after this resampling. With this arrangement of the data, one can compare multiple runs, e.g., by calculating averages and standard deviations at each integer degree.

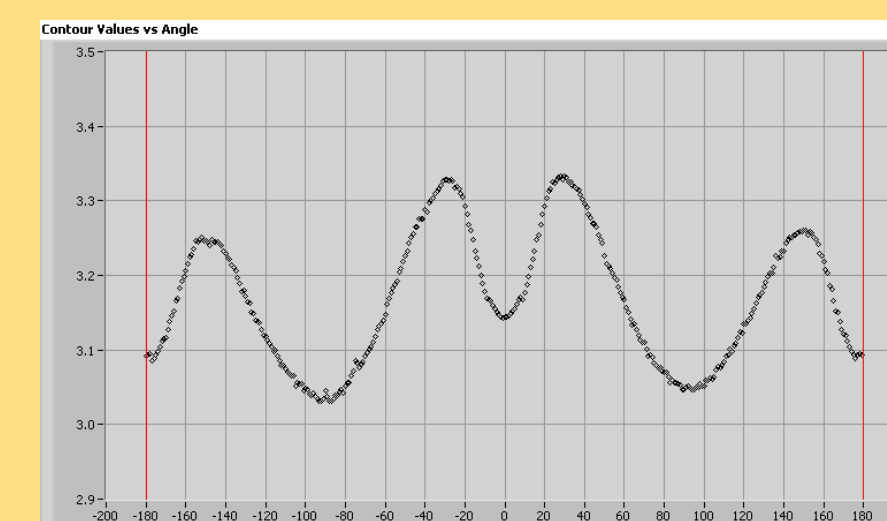


Figure 8. Shape graph (averaged and resampled)

RESULTS

Multiple Inflations of One Balloon

- A single balloon was inflated and deflated to the same volume 5 times to check consistency. Results are shown as separate data series in the shape graph of Figure 9.
- Consistency is excellent. The lower series in light green shows the standard deviation at each angular point (scale on right). The average standard deviation was 1.1% of the diameter or 0.36 mm.

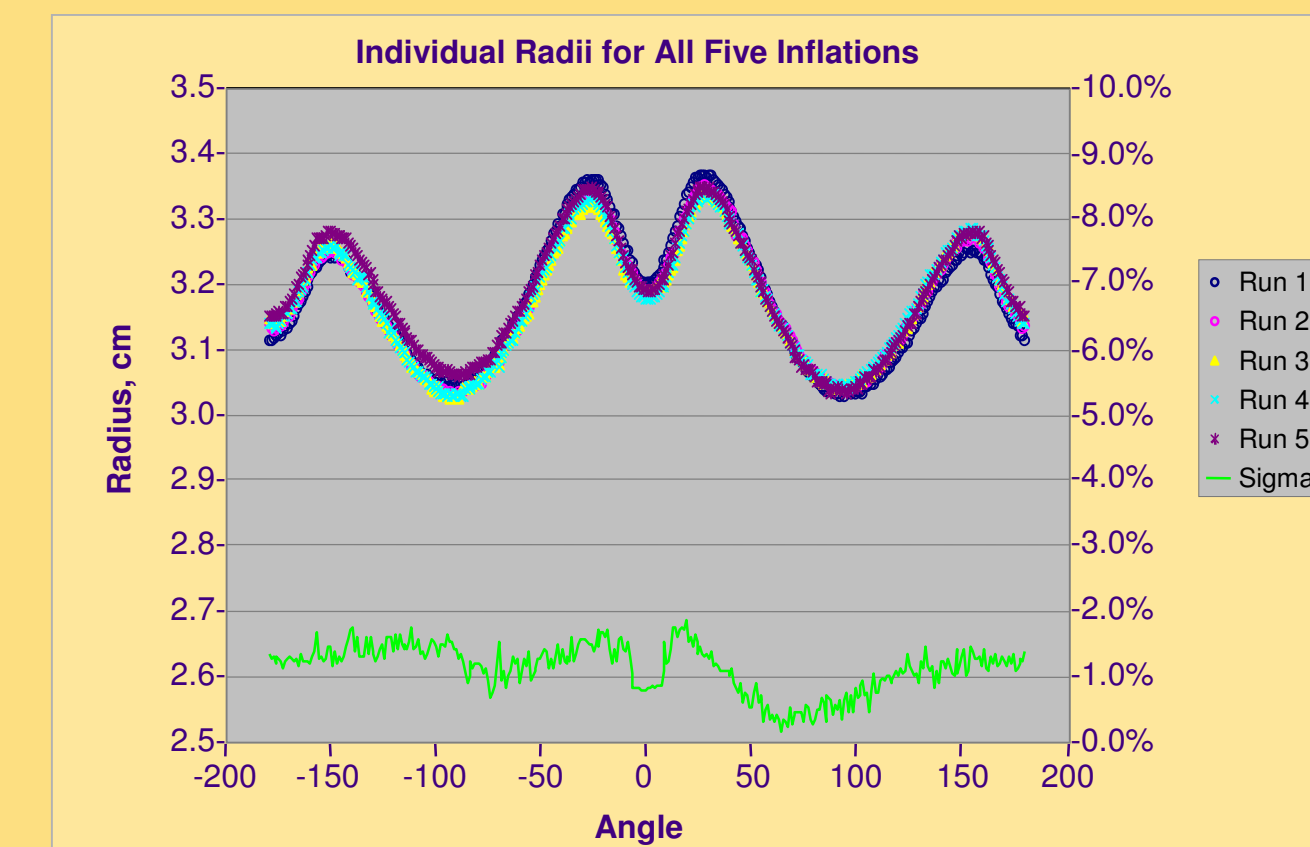


Figure 9. Shape graph for a single balloon inflated and deflated 5 times.

Multiple Balloons Inflated Once

- Consistency between balloons in manufacturing is critical to ensure proper dosimetry in clinical use.
 - Xoft's balloons are routinely and individually checked for leakage, shaft symmetry and gross size.
 - Applying the shape test described here to a set of balloons provides more detailed information on the manufacturing process and greater confidence in what is used for patient treatment.
- Five balloons were randomly selected and inflated to the same volume, then mounted, photographed and processed as described.
- Figure 10 shows the shape graphs for all 5, superimposed. The lower green trace is the standard deviation at each angle. It averages 1.3% or 0.40 mm.
- The average shape coordinates are plotted in Figure 11 as Y vs. X to show the shape in a more traditional manner.

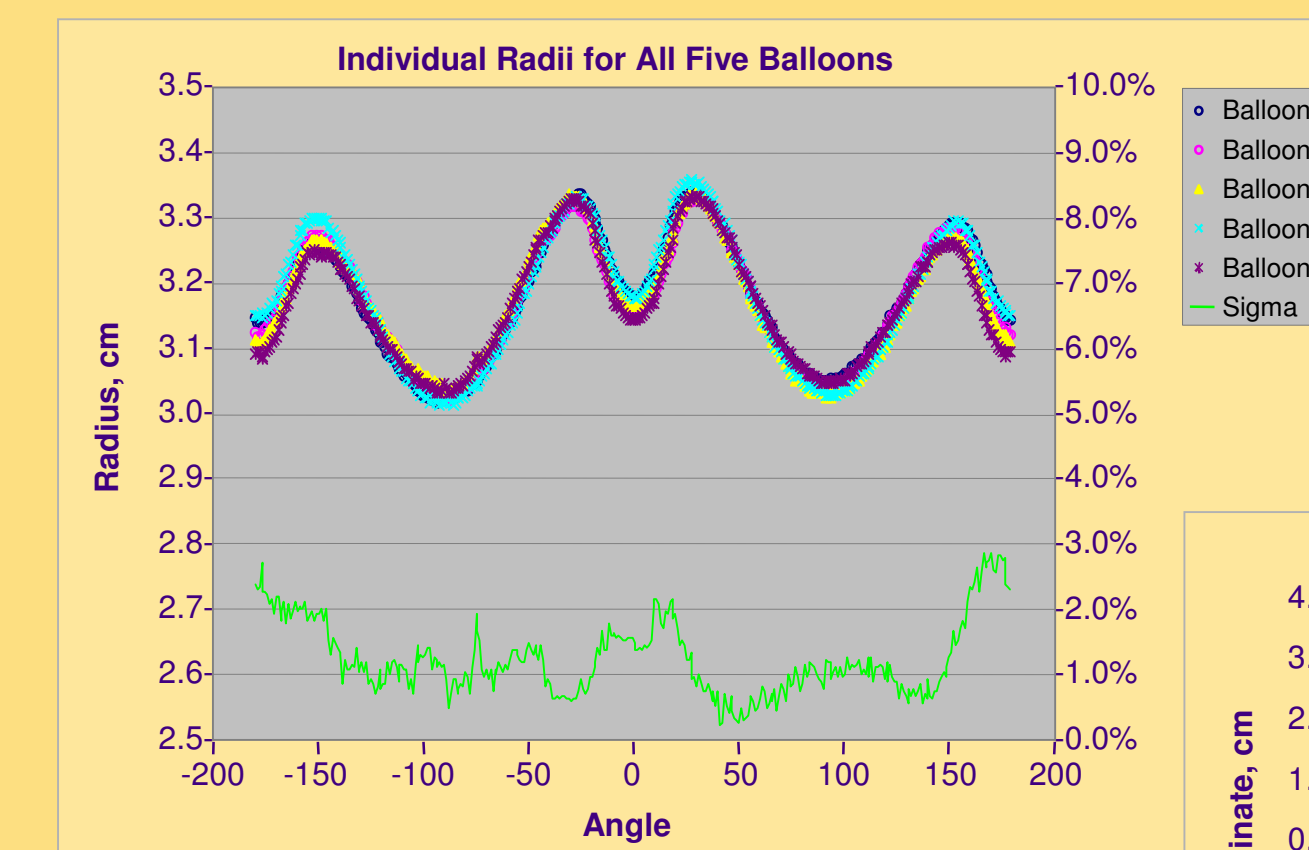


Figure 10. Shape graph for 5 balloons, inflated once

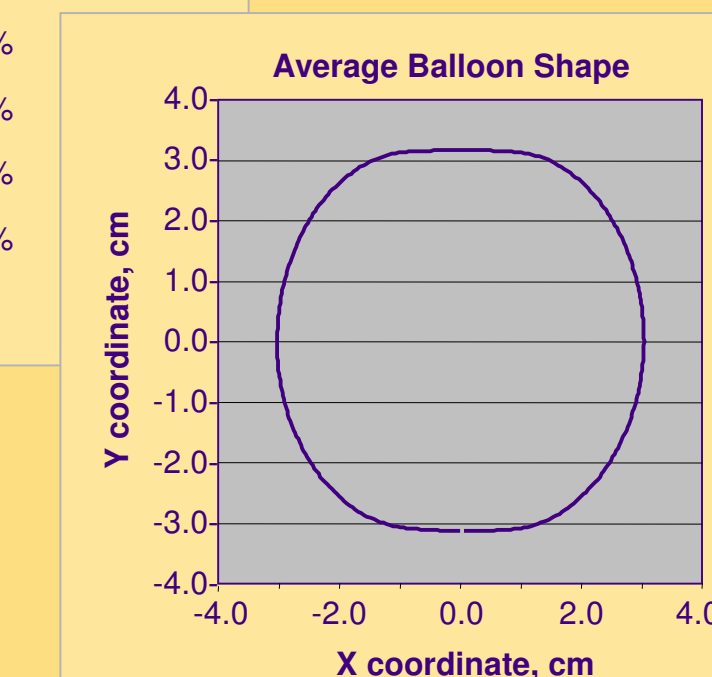


Figure 11. Plot of average shape coordinates

RESULTS

One Balloon at Four Rotations

- Also of interest is the balloon azimuthal symmetry. This can be determined by viewing a balloon from several angles around the shaft axis.
- Figure 12 shows results from a single balloon photographed at 90° increments. Maximum variation is on the order of 0.5 mm, with an average $\sigma = 2.2\%$ of the local diameter or about 0.70 mm.

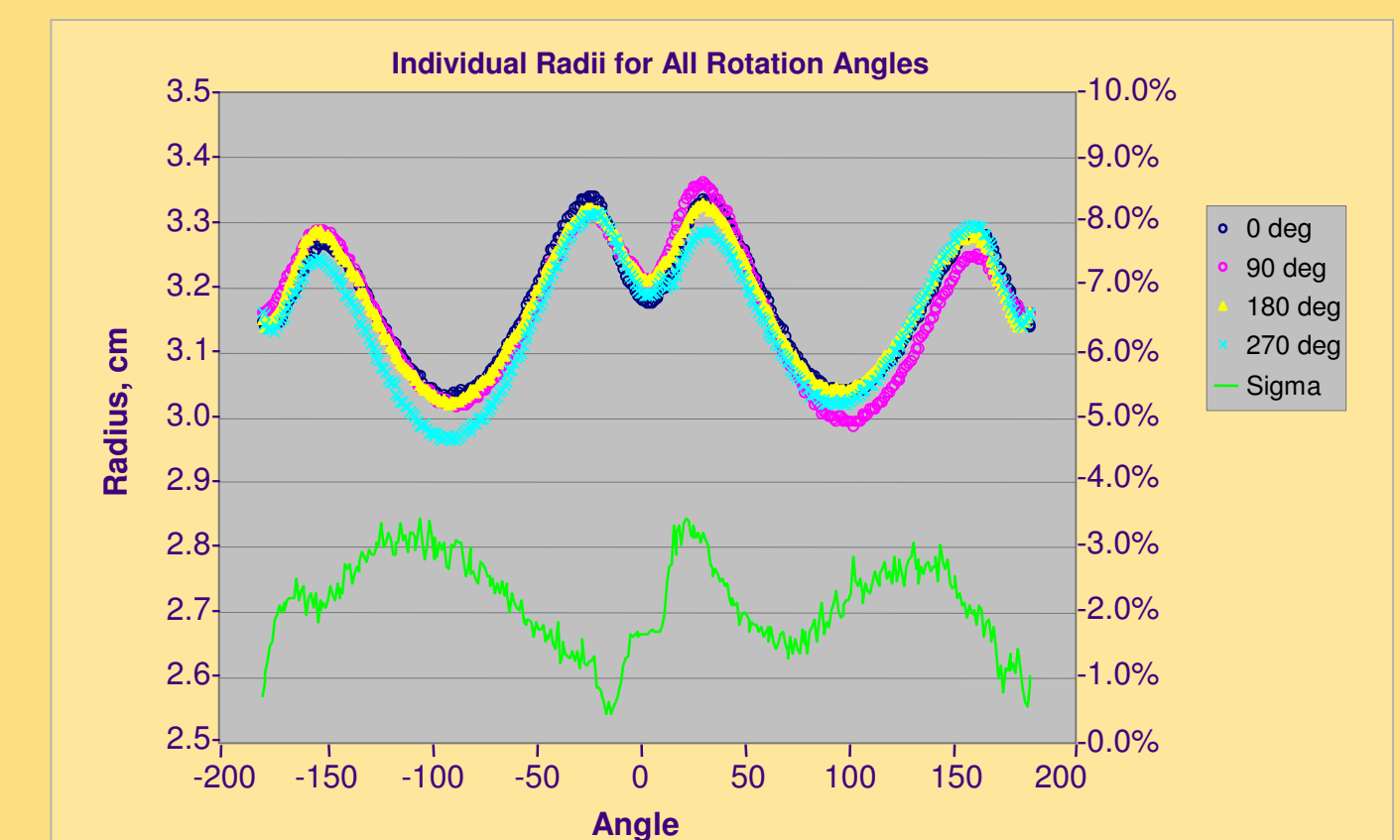


Figure 12. Shape graph of 1 balloon at 4 rotations

SUMMARY

- A new technique has been developed to quantify the shape of brachytherapy balloons. The technique uses digital photography and both standard and custom developed image processing algorithms. It allows rigorous comparisons of re-inflation consistency, balloon to balloon consistency, and rotational symmetry. Results of these tests on Xoft balloons are summarized in Table 1.

Test	Avg radius, cm	Avg σ	Avg σ , mm
Rotation	3.17	2.2%	0.70
Re-inflation	3.18	1.1%	0.36
Multiple balloons	3.18	1.3%	0.40

- The technique can be used to sample test manufactured product, qualify new OEM vendors, and compare the shapes of balloons from different producers. It can also be applied to items other than balloons for quantitative shape characterization.

CONCLUSION

- Presenting a predictably uniform shape is important dosimetrically in any brachytherapy treatment -- especially so in uses such as IORT where CT scan data is not available, and the nominal balloon shape must be assumed in planning the treatment.
- The technique described provided detailed quantitative evaluation of the shape of Xoft Axxent® balloons used in APBI.
- It will be used to qualify a new manufacturing process at the current vendor and to qualify first articles produced by a new vendor.

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