

# Beauty is in the Eye of the Beholder: Cosmetic Outcomes After *Precision Breast* IORT



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## Introduction

Adjuvant radiation (RT) is standard treatment after breast conserving surgery (BCS) for patients with breast cancer. The standard technique is whole breast irradiation (WBI), which consists of 3-5 weeks of daily fractions to the entire breast.

Accelerated partial breast irradiation (APBI) was developed to decrease the number of treatments and the volume of breast tissue that is irradiated. Intraoperative Radiation therapy (IORT) is an extreme form of APBI consisting in one radiation dose at time of BCS.

While WBI is known to result in adequate cosmesis in at least 80% of patients<sup>1</sup>, APBI and IORT have shown mixed results after assessment by physicians and/or patients.

At the University of Virginia, we have developed a novel form of IORT called *Precision Breast IORT (PB-IORT)*, incorporates intraoperative CT imaging and high-dose-rate brachytherapy to deliver a dose of 12.5 Gy to a depth of 1 cm from the balloon surface<sup>2</sup> (Figure 1).

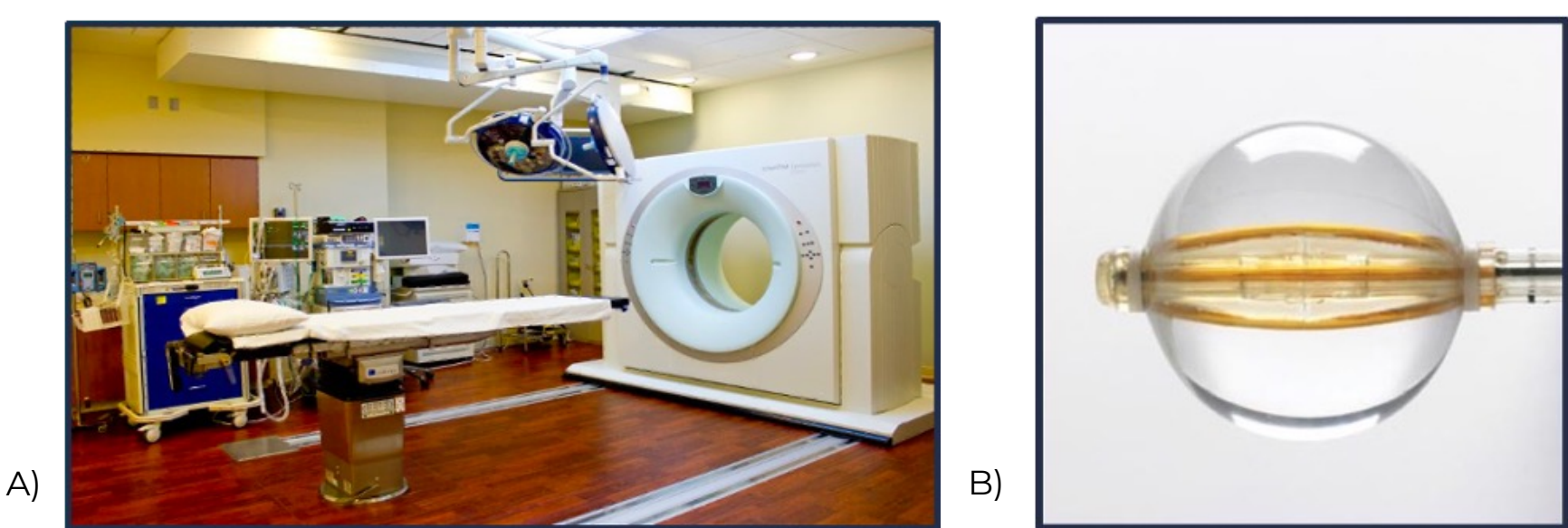


Figure 1: A) Intraoperative CT B) High dose rate multi-lumen catheter

The use of a multi-lumen catheter and CT imaging allows for an individualized radiation dose to be delivered while avoiding radiation to the skin and chest wall (Figure 2).

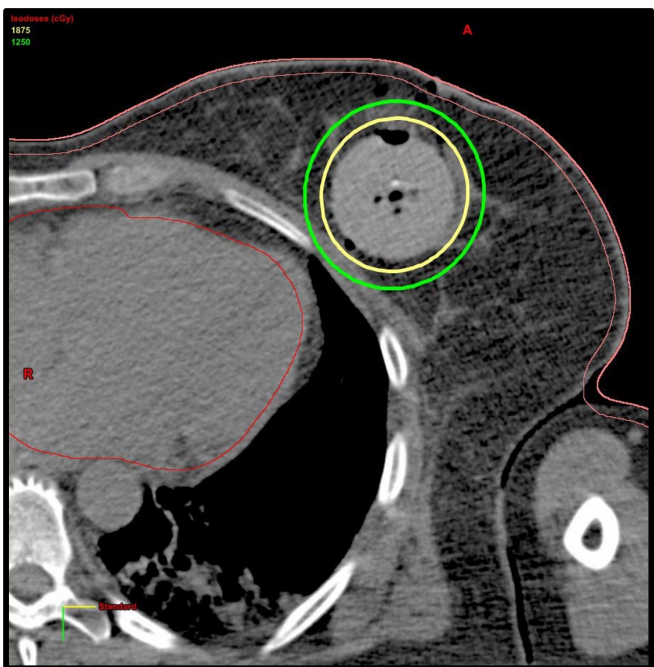


Figure 2: Individualized radiation dose avoiding skin and chest wall

PB-IORT was offered as a phase II, multi-institutional clinical trial from 2015 to 2022. It was found to have similar toxicity rates as conventional IORT and to result in good or excellent cosmesis as evaluated by surgeons at 12 months after treatment<sup>3</sup>.

**Aims:** A) Assess long-term cosmetic results after PB-IORT as rated by breast clinicians, participants, and a plastic surgeon. B) Evaluate inter-rater agreement between evaluators

**Hypothesis:** Majority of patients will have good or excellent cosmesis after PB-IORT and inter-rater agreement will be moderate.

## Methodology

**PB-IORT Clinical Trial Inclusion Criteria:**

- At least 45 years old
- Invasive or in situ carcinoma
- Tumor size ≤3cm
- Pathologically node negative

**Cosmesis Evaluation:**

Breast clinicians, participants, and a plastic surgeon completed cosmesis evaluation at 3, 6, 12, and 24 months after treatment with *PB-IORT*.

Each follow-up visit was evaluated separately and included patients with available data only.

Cosmesis was evaluated using the Harvard Cosmesis Scale (HCS) and a survey assessing three areas of general cosmesis: difference in color, shape, and size between treated and untreated breast (Figure 3).

Harvard Cosmesis Scale	
Treated breast to untreated breast	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor
General Cosmesis	
Color difference between treated and untreated breasts	<input type="checkbox"/> None <input type="checkbox"/> A little <input type="checkbox"/> Some <input type="checkbox"/> Very Much
Size difference between treated and untreated breasts	<input type="checkbox"/> None <input type="checkbox"/> A little <input type="checkbox"/> Some <input type="checkbox"/> Very Much
Shape difference between treated and untreated breasts	<input type="checkbox"/> None <input type="checkbox"/> A little <input type="checkbox"/> Some <input type="checkbox"/> Very Much

Table 1: Harvard cosmesis scale; general cosmesis assessment.

HCS scores were dichotomized into Excellent/Good (E/G) and Fair/Poor (F/P). General cosmesis scores were dichotomized into A little/None (L/N) and Some/Very Much (S/M).

**Inter-rater agreement:**

Kappa statistics were used to measure inter-rater agreement at each follow up visit.

## Results

Final cohort included 357 patients with median age of 63 years and tumor size of 9mm. The number of patients with available cosmesis data at each follow up visit ranged from 279 to 353 (Table 1).

Patient and Tumor Characteristics	N (%)
Age	63 (7.86)
Ethnicity	
Non-Hispanic	345 (96.6)
Tumor size (mm)	9 (6.77)
Hormone Receptor	
ER +	334 (93.6)
Tumor type	
Ductal Carcinoma In Situ (DCIS)	102 (28.6)
Invasive ductal carcinoma (IDC)	98 (27.5)
Invasive lobular carcinoma (ILC)	21 (5.9)
DCIS & IDC	123 (34.5)
Other	13 (3.6)

Table 2: Sample population characteristics

## Results

**Cosmesis evaluation:**

At 24 months, most patients were rated as having **E/G** cosmesis. The rate of patients self-reporting satisfactory cosmesis was lower than the rate reported by the breast clinicians but higher than the rate reported by the plastic surgeon. At least 90% of patients were rated as having **L/N** in color by all raters. The proportion of patients scored as having **L/N** in shape at 24 months ranged from 77 to 89%, with the lowest rate given by the plastic surgeon. Approximately 88% of patients were scored as having **L/N** in size by all raters (Figure 4).

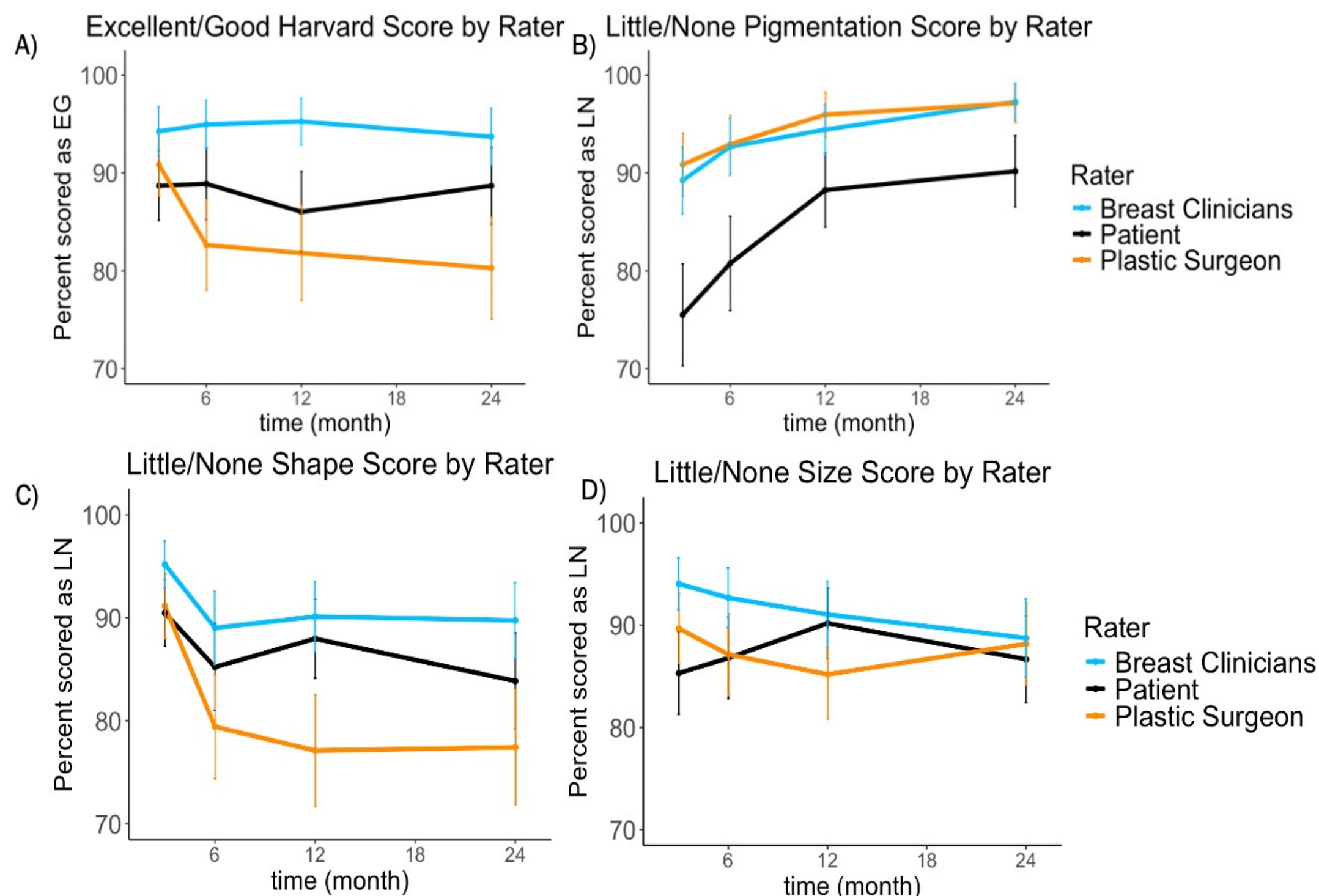


Figure 3: A) Rates of Excellent/Good Harvard cosmetic scale scores per rater over time. B) Rates of little/ none change in pigmentation per rater over time. C) Rates of little/ none change in Shape per rater over time. D) Rates of little/ none change in size per rater over time.

**Inter-rater agreement**

The highest kappa score seen between all evaluators was 0.29 at the 12-months change in shape assessment (Table 3.) Agreement between raters was considered fair since a kappa score of 0.41 is needed for moderate agreement. Figure 4 shows examples of high and low agreement between raters.

Follow up time (month)	Harvard Scale Inter-rater agreement (k)	Pigmentation changes Inter-rater agreement (k)	Shape changes Inter-rater agreement (k)	Size changes Inter-rater agreement (k)
3	0.144	0.200	0.226	0.155
6	0.104	0.238	0.258	0.234
12	0.270	0.242	0.290	0.260
24	0.276	0.177	0.273	0.263

Table 3: Inter-rater agreement in cosmetic outcomes evaluation between breast clinicians, patients, and plastic surgeon.

## Results

**Cosmesis assessment and interrater agreement:**

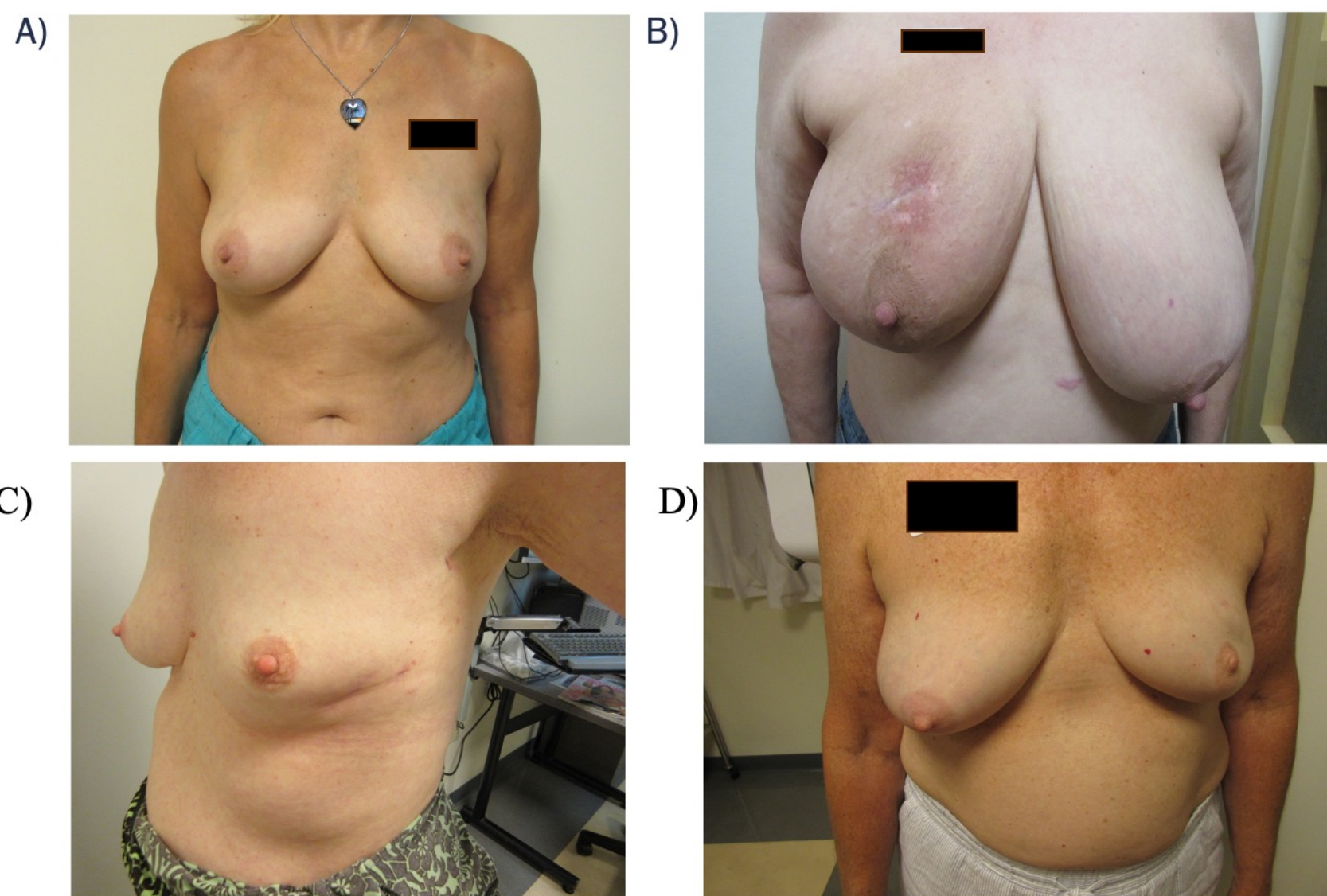


Figure 4: A) High agreement: All evaluators rated HCS as E/G. B) High agreement: All evaluators rated HCS as F/P. C) Low agreement: The breast clinicians and the plastic surgeon rated change in color L/N while the patient reported S/M change. D) Low agreement: The breast clinicians and patient rated change in shape as L/N, while the plastic surgeon rated it S/M.

## Conclusion

**Precision breast IORT** delivers a high radiation dose of customized radiation resulting in **excellent** cosmetic outcomes.

There was **minimal agreement** between breast clinicians, patients, and the plastic surgeon for all variables

Future studies should include patient-reported outcomes as the primary means of evaluating cosmesis after breast cancer surgery.

## References

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