



Cosmetic Outcome from Post Lumpectomy
Whole Breast Irradiation (WBI) Versus
Partial Breast Irradiation (PBI) on the NRG
Oncology/NSABP B39-RTOG 0413 Phase III
Clinical Trial

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Disclosures for Dr. White

- I have no conflicts of interest to disclose.

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NSABP B-39/RTOG 0413 Study Design

Selected Eligibility Criteria

- Lumpectomy
- Stage 0, I, II
- Tumor size ≤ 3.0 cm
- Negative margins (No ink on tumor)
- N0, N1 ≤ 3 positive nodes
- Age >18

RANDOMLY ASSIGNED

STRATIFICATION

- Disease Stage (DCIS; Invasive N0; Invasive N1)
- Menopausal Status (pre- and post-)
- Hormone Receptor Status (ER and/or PR+; ER- and PR-)
- Intention to Receive Chemotherapy

Whole Breast Irradiation (WBI)

50 Gy (2.0 Gy/fraction) or
50.4 Gy (1.8 Gy/fraction) to whole breast,
followed by optional boost to ≥ 60 Gy

5-6 weeks

Partial Breast Irradiation (PBI)

10 fractions/ BID / **5-8 days**
34 Gy in 3.4 Gy fractions Interstitial
Brachytherapy or Mammosite Balloon Catheter
Or 38.5 Gy in 3.85 Gy fractions 3DCRT

QOL SubStudy: **Cosmetic Outcome Assessments**

- 975 enrolled from March 2005 to May 2009
- 900 (420 CT and 480 no-CT) had baseline forms and at least one PT/Site MD/DP Review at 12 or 36 months
- **Global Cosmetic Score (GCS):** Patient (PT) and MD (Site)
 - 4 Point Scale NRG-RTOG
 - 1-Excellent, 2-Good, 3-Fair, 4-Poor
- Digital Photos (DP):
 - Both breasts and close-up of treated breast
 - Submitted separate database
- Time points:
 - PT – baseline; last day of treatment; 4 weeks, 6,12, 24, and 36 months after treatment
 - MD – baseline; 12 and 36 months after treatment
 - DP – baseline; 12 and 36 months after treatment

Change in GCS at 36 months

NRG/NSABP B39-RTOG 0413: Comparing Cosmetic Outcome between Treatment Arms - PBI and WBI

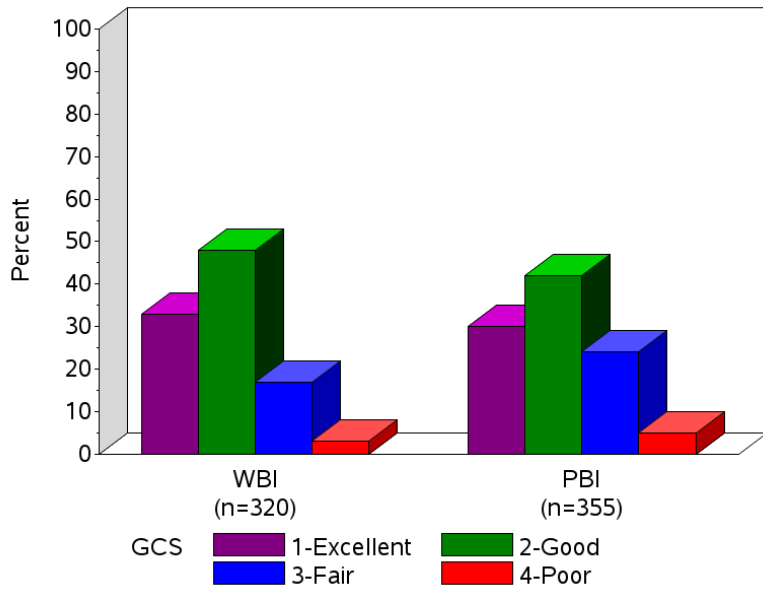
$\Delta^{\dagger} = [36\text{-Month Scores} - \text{Baseline Scores}]$		Δ^{\dagger} in GCS by Patient	Δ^{\dagger} in GCS by Site MD	Δ^{\dagger} in GCS by DP Central MD Review
Chemo	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size:	n=307 0.06 (-0.14 to 0.25) -0.35 to 0.35 Equivalent 0.06	n=261 0.27 (0.02 to 0.53) -0.42 to 0.42 NOT Equivalent (PBI worse) 0.26	n=191 0.18 (-0.09 to 0.44) -0.37 to 0.37 NOT Equivalent (PBI worse) 0.19
Non-Chemo	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size	n=368 0.04 (-0.15 to 0.22) -0.35 to 0.35 Equivalent 0.04	n=343 0.16 (-0.01 to 0.33) -0.33 to 0.328 NOT Equivalent (PBI worse) 0.19	n=213 -0.20 (-0.42 to 0.01) -0.31 to 0.31 NOT Equivalent (WBI worse) -0.26
Combined*	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size	n=675 0.04 (-0.09 to 0.17) -0.35 to 0.35 Equivalent 0.045	n=604 0.20 (0.05 to 0.35) -0.37 to 0.37 Equivalent 0.22	n=404 -0.024 (-0.19 to 0.14) -0.34 to 0.34 Equivalent -0.028

*Chemo Use Groups

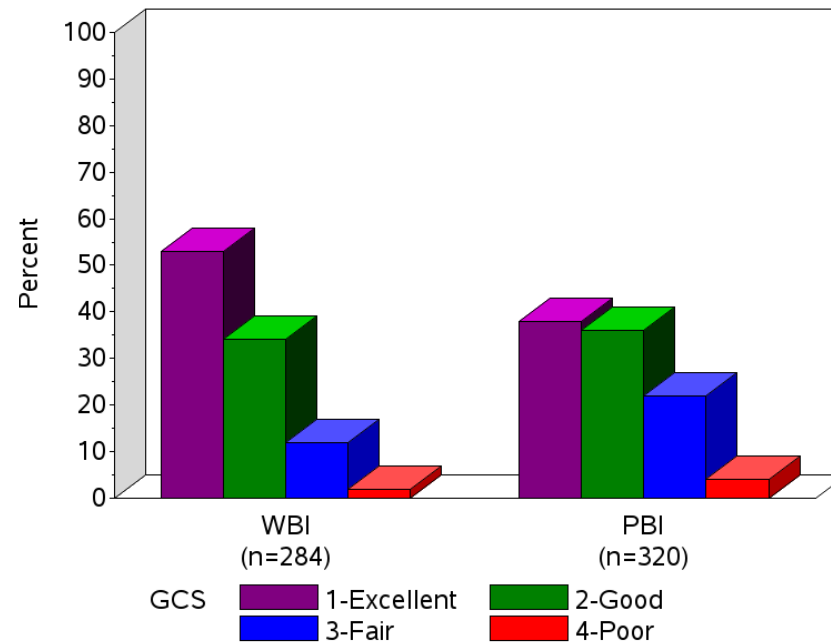
36-Month Global Cosmetic Score (GCS) by Treatment Arm

All Patients

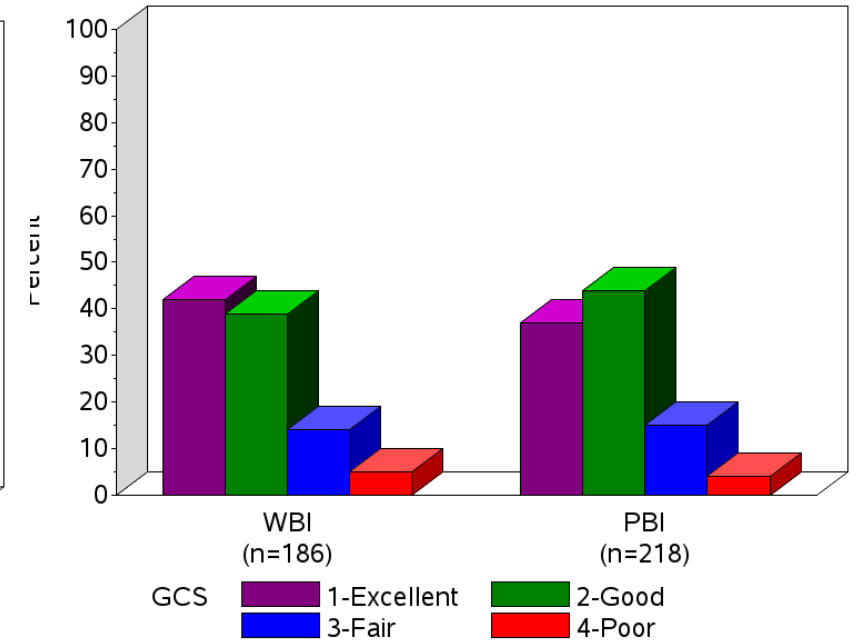
Patient



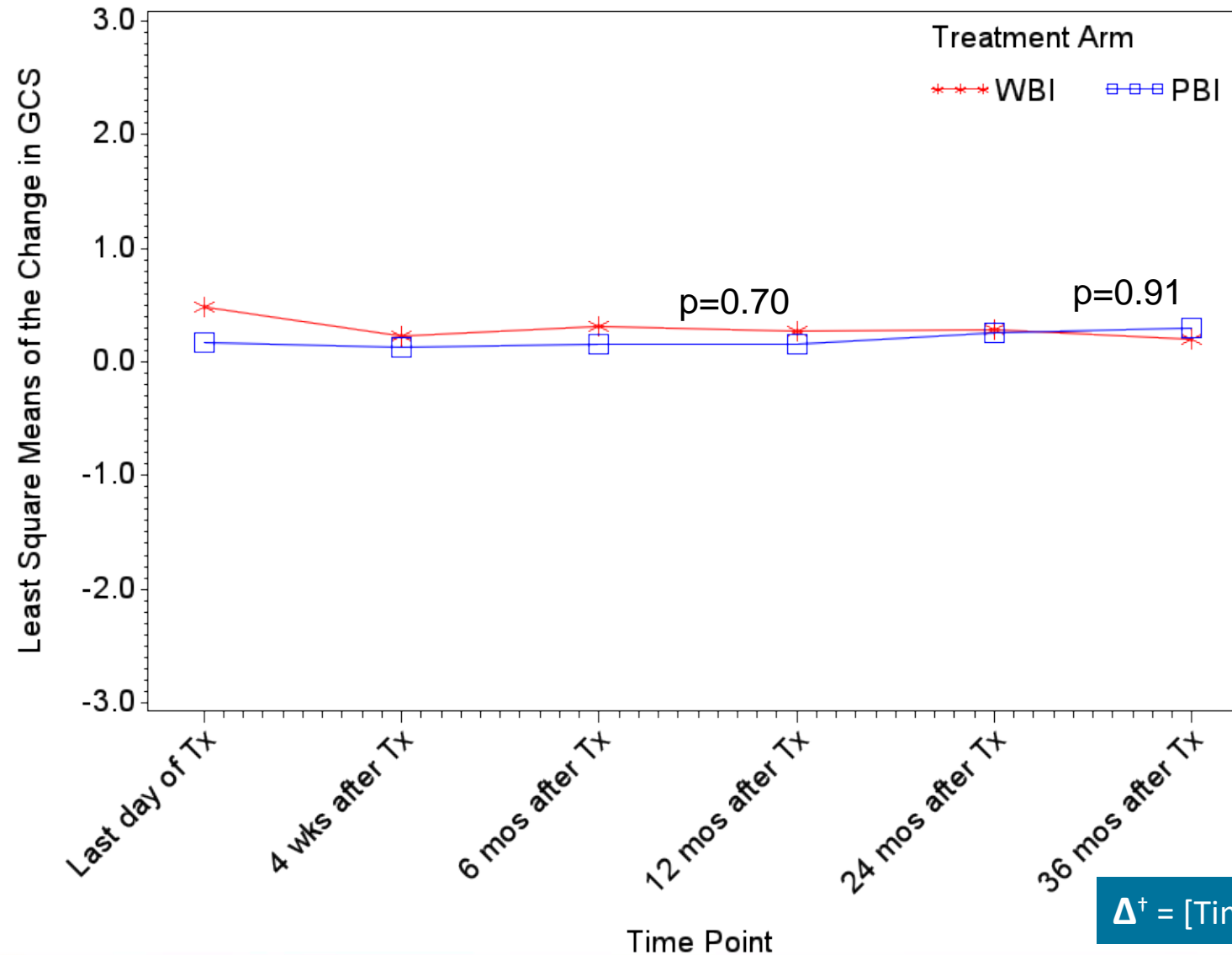
Site MD



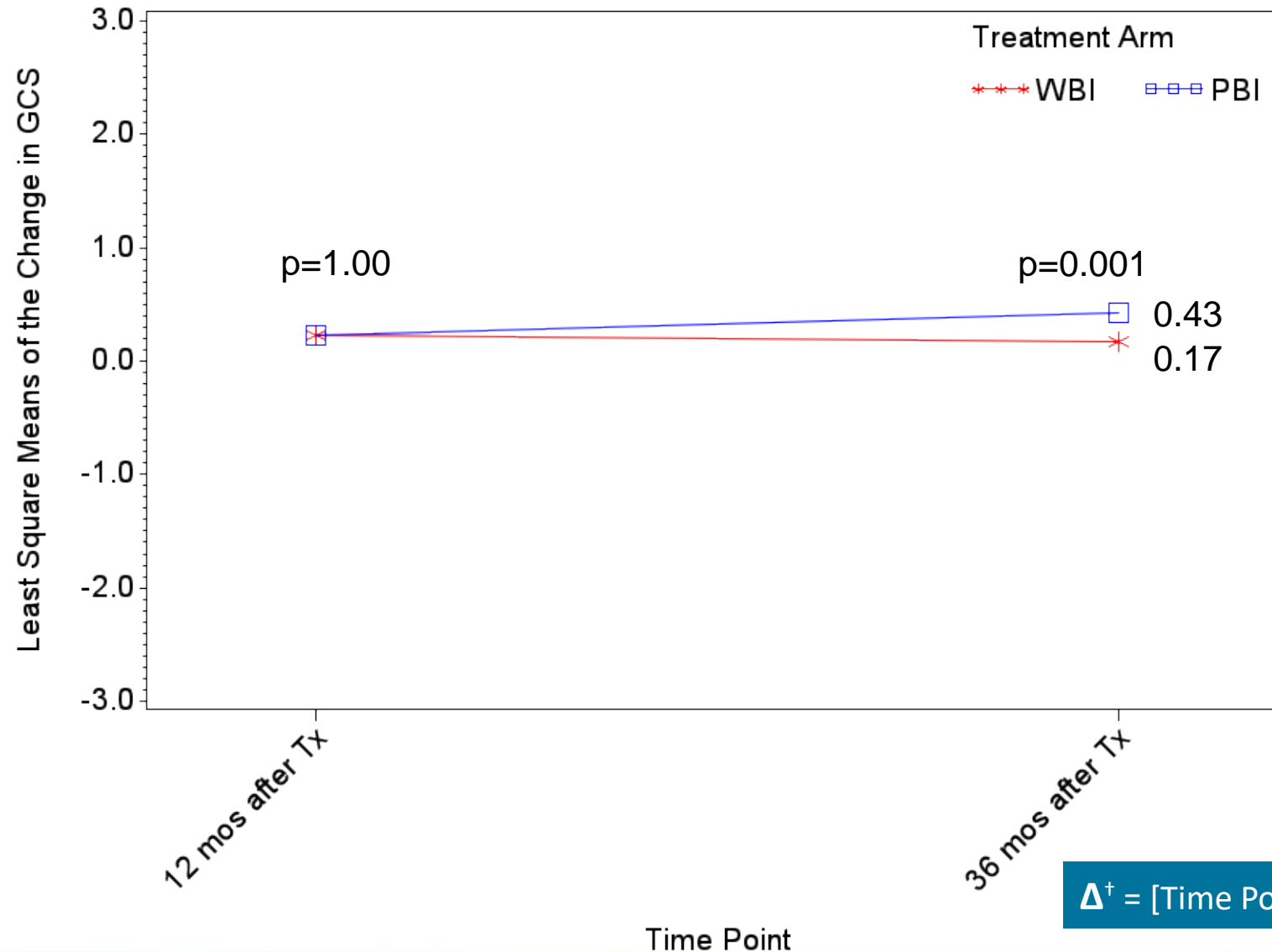
DP MD Review



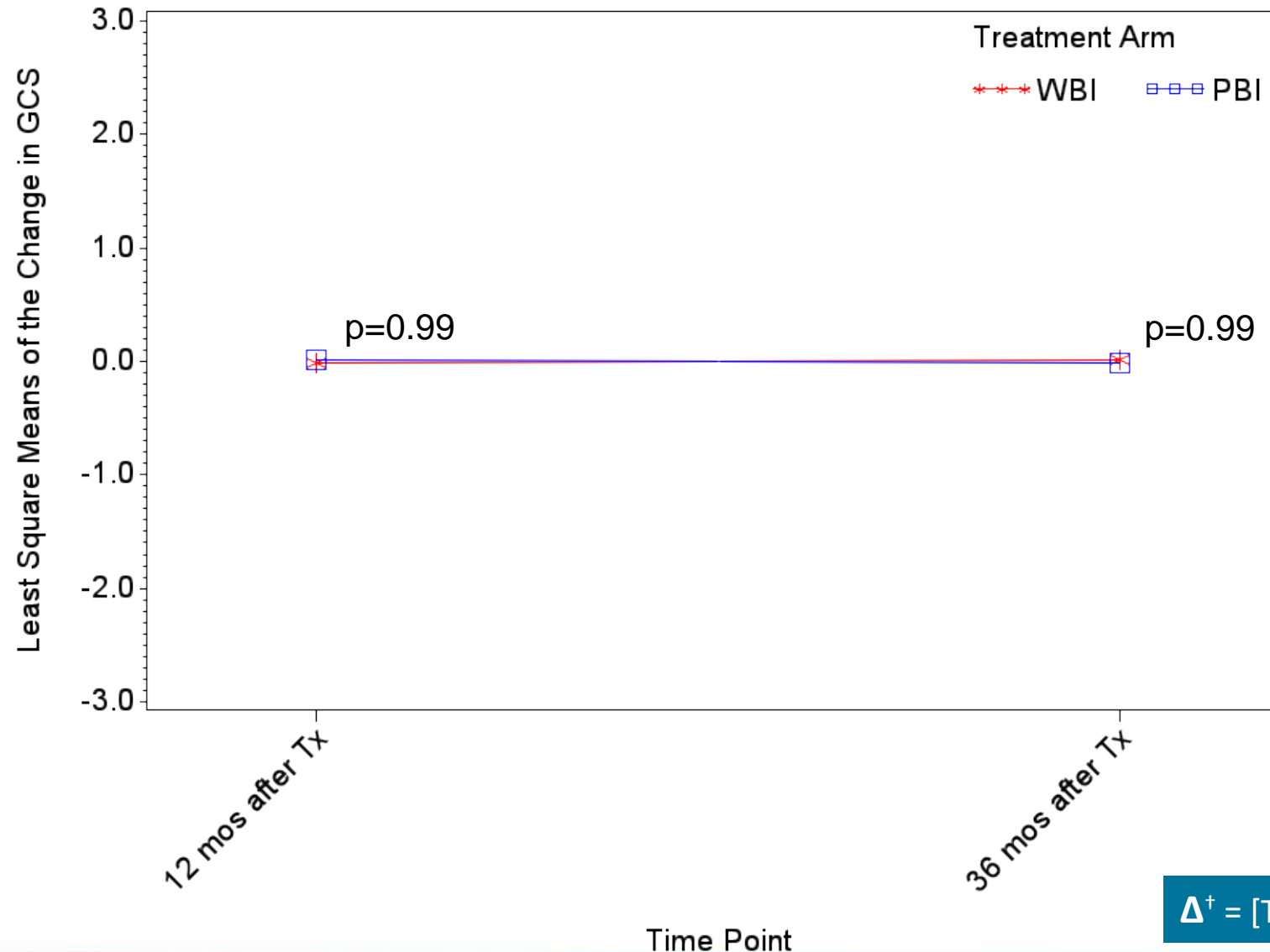
Adjusted Mean Change (Δ^{\dagger}) in GCS by Patient at Each Time Point



Adjusted Mean Change (Δ^{\dagger}) in GCS by Site MD at Each Time Point



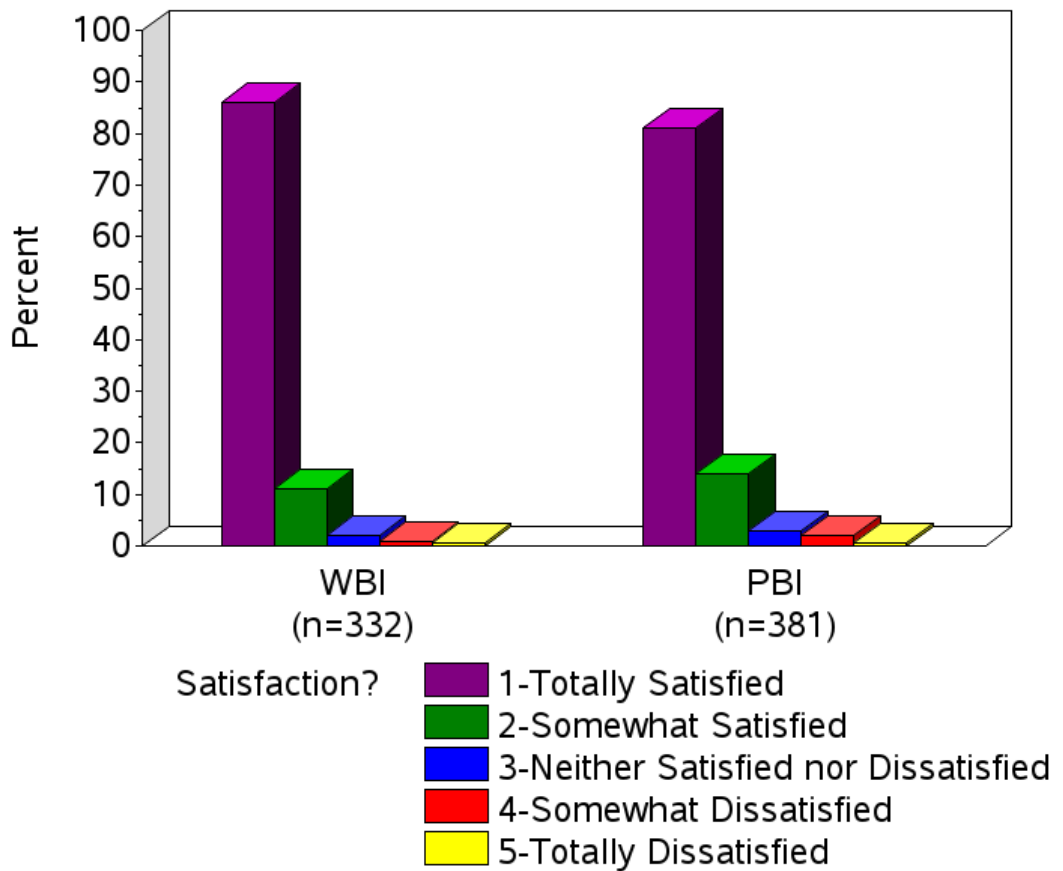
Adjusted Mean Change (Δ^+) in GCS by MD Central Digital Photo Review at Each Time Point



Δ^+ = [Time Point Scores - Baseline Scores]

Patients' Satisfaction with Treatment and Cosmetic Outcome

At 36 Months



Change (Δ^{\dagger}) in Patients' Satisfaction

Chemo	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size:	n=327 0.013 (-0.18 to 0.21) -0.36 to 0.36 Equivalent 0.014
Non-Chemo	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size:	n=386 0.045 (-0.13 to 0.22) -0.34 to 0.34 Equivalent 0.053
Combined	Diff (μ PBI- μ WBI): 95%CI: Bound: Effect Size:	n=713 0.03 (-0.10 to 0.16) -0.35 to 0.35 Equivalent 0.035

$\Delta^{\dagger} = [36\text{-Month Scores} - \text{Baseline Scores}]$

Conclusions

- Patient rated cosmetic outcome based on the GCS was equivalent for PBI and WBI.
- Accruing site MDs rated cosmetic outcome worse at 36 months for PBI. The change in cosmetic outcome over time was equivalent for PBI and WBI.
- Digital photo cosmetic outcome rated by MDs blinded to treatment arm and time point was equivalent for PBI and WBI.
- Patient Satisfaction was equivalent for PBI and WBI.