

Assessing Cellulite Severity: Method for Assessing Reliability of a New Clinician-Reported and a New Patient-Reported Photonumeric Scale

PRM121

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BACKGROUND

- Cellulite is a common condition in women, occurring in up to 98% of them¹
- Currently, few validated scales (eg, Hexsel Cellulite Severity Scale [CSS]²) are available to evaluate the severity of cellulite
- The Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS; Figure 1) and Patient Reported Photonumeric Cellulite Severity Scale (PR-PCSS; Figure 2) are 5-point photonumeric scales that have been recently developed to assess cellulite severity
 - Test-retest reliability has been established for the PR-PCSS and for the CR-PCSS using photographs
 - These 2 scales have been shown to correlate with traditional measures of cellulite severity (eg, CR-PCSS with Hexsel CSS; PR-PCSS with the Subject Global Aesthetic Improvement Scale)³

AIM

- To further validate through in-person assessments the use of the CR-PCSS (by clinicians) and the PR-PCSS (by patients) for cellulite severity on buttocks and posterolateral thighs

METHODS

- Noninterventional test-retest reliability study using in-person assessments
- The CR-PCSS (Figure 1) and PR-PCSS (Figure 2) are a series of 5 photographs ranked in increasing order of cellulite severity according to the number and depth of dimples on the left or right buttocks and left or right posterolateral thighs, with corresponding labels and text descriptors
 - Content validity of both scales (eg, descriptors) was previously established through concept elicitation and cognitive interviews

Figure 1. CR-PCSS for Buttock and Thigh



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CR-PCSS = Clinician Reported Photonumeric Cellulite Severity Scale.

- Training on the use of CR-PCSS included an online video and in-person instruction at baseline using live models
- Target patient enrollment for live assessments was 16 females (≥18 years of age) at each of the 5 levels of cellulite severity (none to severe)
- CR-PCSS test-retest involved assessments at baseline and Day 2
- Various methods were used to minimize clinician recall bias (eg, rating a large number of patients, changing the order of evaluations on Day 2, visual field limited only to areas under evaluation, no physical contact or verbal interactions with patient)
- Patients rated by clinicians also self-rated their cellulite severity using the PR-PCSS on Day 1 and on Day 14 (+3 days as needed for ease of scheduling); the 2-week interval was to reduce memory bias
 - Patients were randomly assigned to use photos (viewed on computer monitor) or a mirror for the Day 1 assessment; the other method was used on the Day 14 assessment

Figure 2. PR-PCSS for Buttock and Thigh



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PR-PCSS = Patient Reported Photonumeric Cellulite Severity Scale.

- Intra- and inter-rater reliability for the CR-PCSS was determined by calculating intraclass correlation coefficients (ICCs) and 95% confidence intervals (CIs)⁴ at baseline and Day 2
 - ICC >0.70 was considered adequate⁵
- Reliability between photograph versus mirror evaluation methods for the PR-PCSS were also determined by calculating ICC and 95% CI
- Concordance between the CR-PCSS and PR-PCSS was determined by comparing CR-PCSS ratings from randomly selected clinicians with pooled (baseline and Week 2) self-ratings of photographs or mirrors for each patient (PR-PCSS)

RESULTS

- 6 clinicians (3 plastic surgeons and 3 dermatologists) were included in the test-retest study (83.3% male; 18.0 median years in practice post residency)
- 81 patients were enrolled; 76 (Table 1) participated in the CR-PCSS and 75 patients participated in the PR-PCSS

Table 1. Patient Demographics and Baseline Characteristics^{*}

Parameter	Patients (n=76)
Age, y, mean (range)	45.1 (18.0-71.0)
Race, n (%)	
White	53 (69.7)
Black or African American	22 (28.9)
Other	1 (1.3)
Cellulite location, n (%)	
Thighs	14 (18.4)
Buttocks	3 (3.9)
Both	58 (76.3)
N/A (no cellulite diagnosis)	1 (1.3)
BMI, n (%)	
Underweight (<18.5 kg/m ²)	1 (1.3)
Normal weight (18.5 to <25 kg/m ²)	28 (36.8)
Overweight (25 to <30 kg/m ²)	16 (21.1)
Obese (≥30 kg/m ²)	31 (40.8)
Fitzpatrick Scale skin category, n (%)	
I (pale white)	1 (1.3)
II (fair)	16 (21.1)
III (darker white)	34 (44.7)
IV (light brown)	10 (13.2)
V (brown)	5 (6.6)
VI (dark brown/black)	10 (13.2)

^{*}The patient population included in the Clinician Reported Photonumeric Cellulite Severity Scale assessment (n=76) differed from the Patient Reported Photonumeric Cellulite Severity Scale assessment (n=75) due to discontinuation/failure to participate. BMI = body mass index.

- CR-PCSS intra-rater reliability for the 6 clinicians was calculated between baseline and Day 2 (Table 2); overall mean ICC point estimates were ≥0.78 for all 4 body locations indicating adequate intra-rater reliability

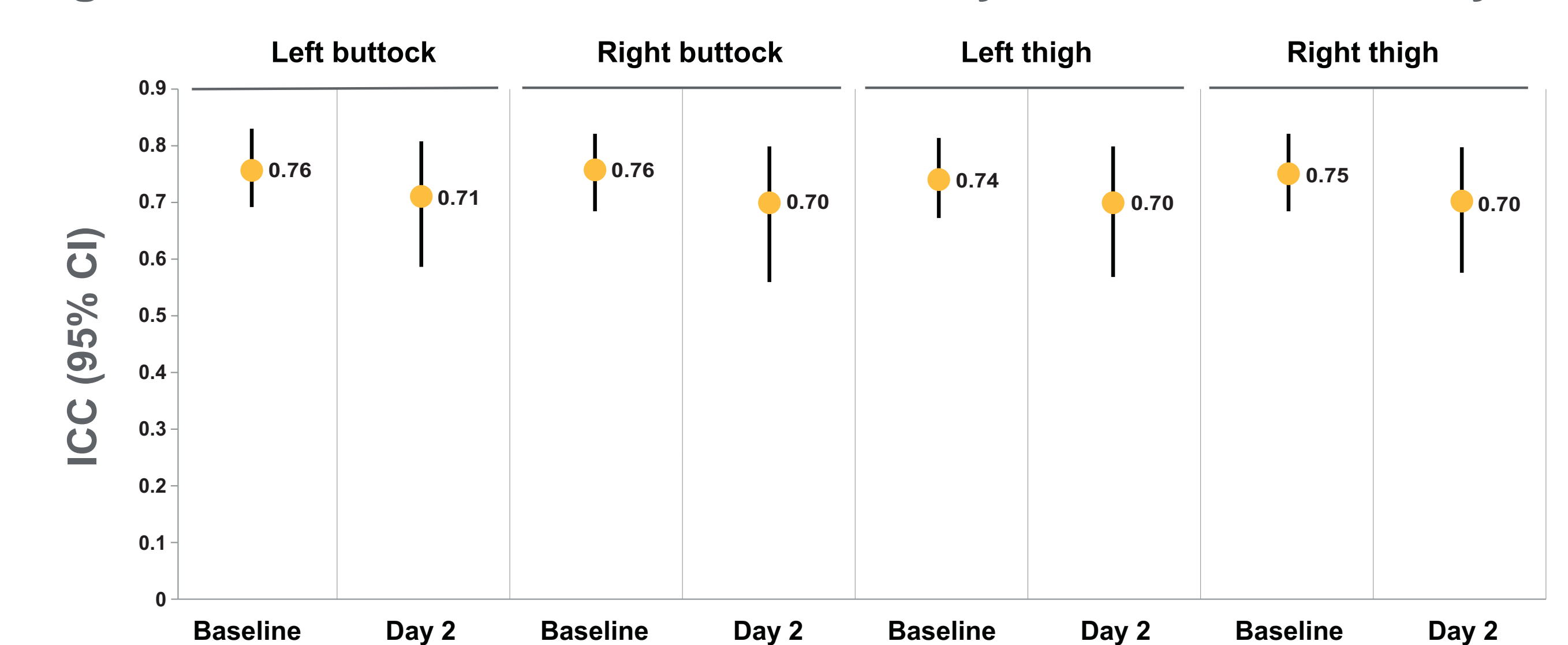
Table 2. Overall CR-PCSS Intra-Rater Reliability^{*}

Cellulite Location	ICC	
	Mean (SD)	95% CI
Left buttock	0.81 (0.08)	0.73, 0.90
Right buttock	0.81 (0.09)	0.72, 0.90
Left thigh	0.78 (0.11)	0.67, 0.90
Right thigh	0.79 (0.11)	0.67, 0.90

^{*}n=6 clinicians. CI = confidence interval; CR-PCSS = Clinician Reported Photonumeric Cellulite Severity Scale; ICC = intraclass correlation coefficient; SD = standard deviation.

- CR-PCSS inter-rater reliability among the 6 clinicians was calculated at baseline and at Day 2 (Figure 3); all ICCs were ≥0.70

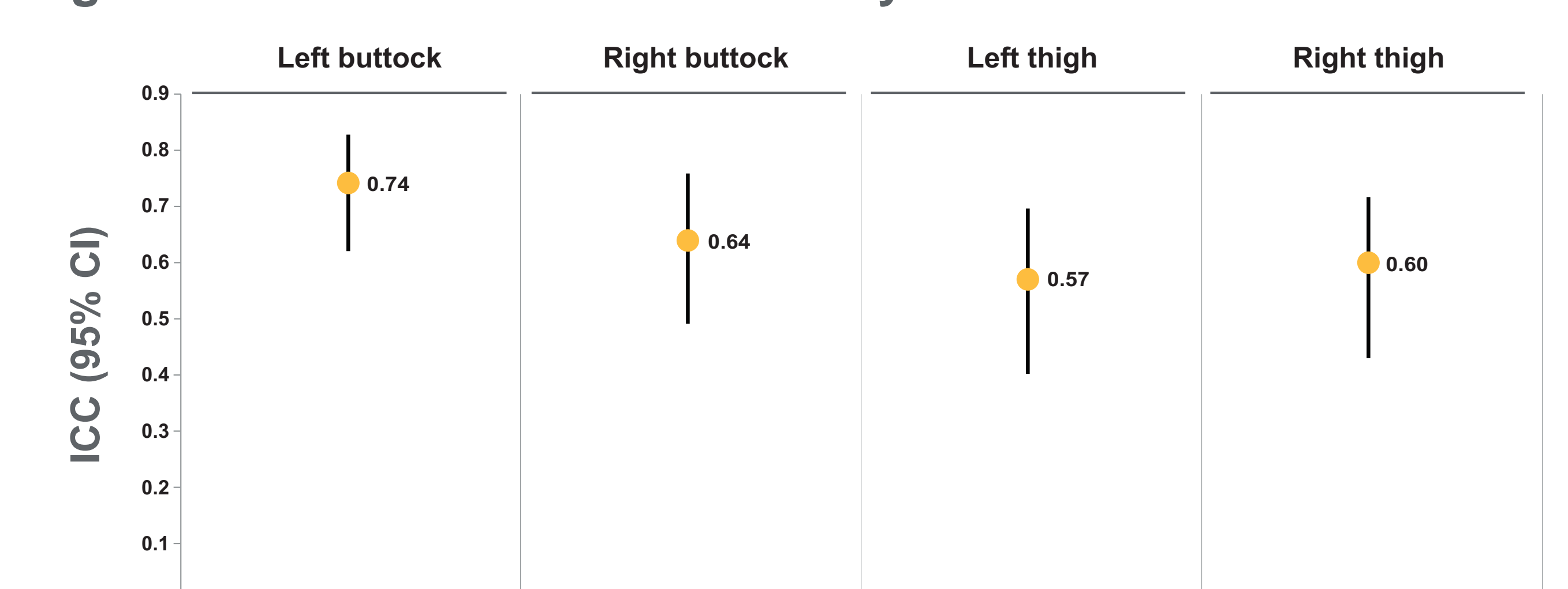
Figure 3. CR-PCSS Inter-Rater Reliability at Baseline and Day 2^{*}



^{*}n=6 clinicians. CI = confidence interval; CR-PCSS = Clinician Reported Photonumeric Cellulite Severity Scale; ICC = intraclass correlation coefficient.

- PR-PCSS intra-rater reliability was determined for the 2 methods of assessment (photographs and mirrors; Figure 4); the ICC values varied by cellulite body location, with adequate reliability observed for the left buttock

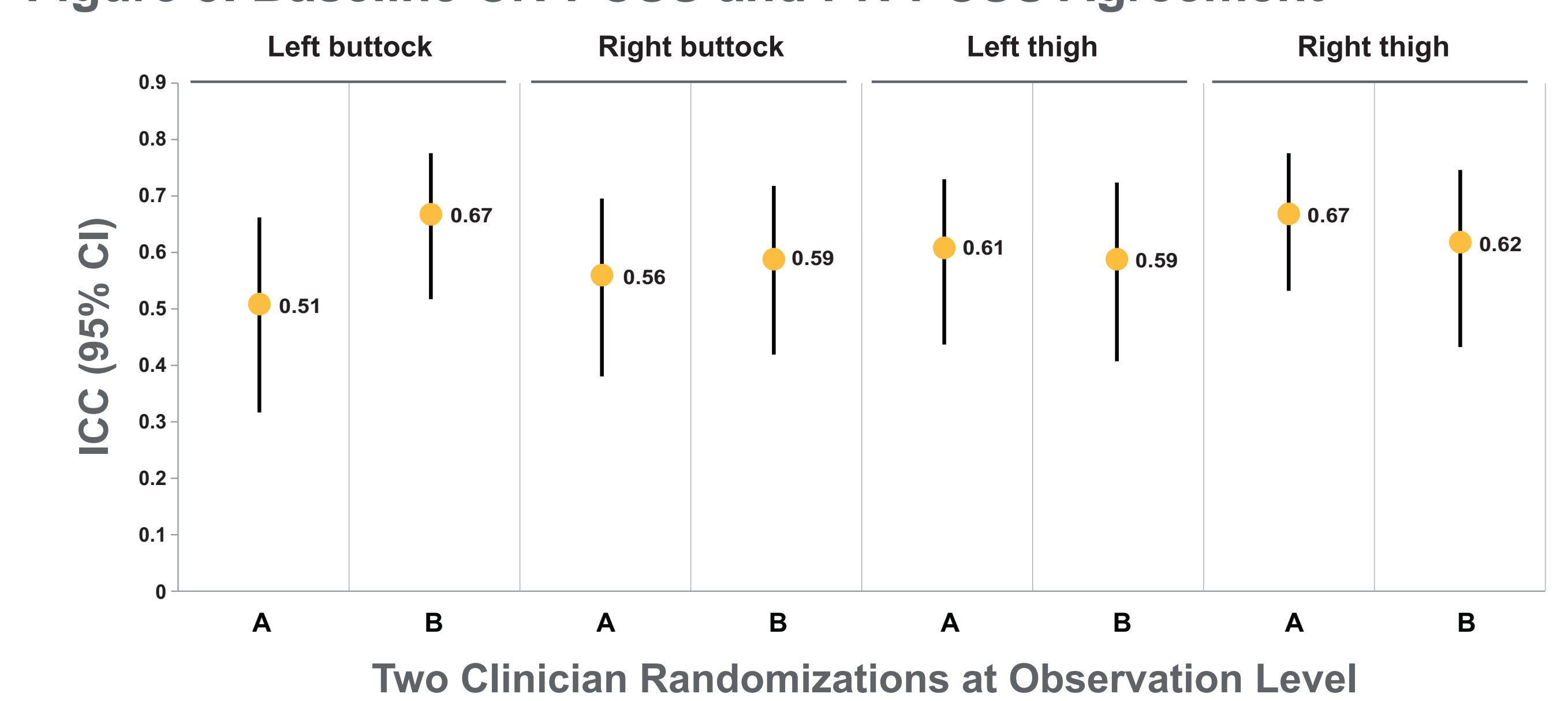
Figure 4. Mean Intra-Rater Reliability for the PR-PCSS^{*}



^{*}n=75 patients (photograph and mirror). CI = confidence interval; ICC = intraclass correlation coefficient; PR-PCSS = Patient Reported Photonumeric Cellulite Severity Scale.

- Cellulite severity agreement between 2 randomly selected clinician ratings and patient pooled assessments ranged from 0.51 to 0.67 for the 4 body locations (Figure 5)

Figure 5. Baseline CR-PCSS and PR-PCSS Agreement^{*}



^{*}Inter-rater reliability between 2 randomizations of clinician data (each observation randomly selected from among the 6 clinicians) and patient (n=76) ratings pooled over the 2 methods (photographs and mirrors). The clinician randomization was executed twice (A and B). CI = confidence interval; CR-PCSS = Clinician Reported Photonumeric Cellulite Severity Scale; ICC = intraclass correlation coefficient; PR-PCSS = Patient Reported Photonumeric Cellulite Severity Scale.

CONCLUSIONS

- The CR-PCSS, using live assessment, was considered reliable for cellulite severity in the thighs and buttocks
- The CR-PCSS and the PR-PCSS produced acceptably comparable ratings of cellulite severity, based on the ICC analysis used
- The CR-PCSS and the PR-PCSS are valid and reliable tools and should be considered for evaluating cellulite severity in clinical trials and real-world settings

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DISCLOSURES

MTK, MPM, DH, GL, and JAD report being employees of Endo Pharmaceuticals Inc. WRL, RB, JC, and NK report being employees of Evidera.

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