Reliability of Sacral Slope, Pelvic Femoral Motion and Cup Ante-inclination on AP Pelvic Radiographs in Healthy Pts

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Statistical Analysis Plan (SAP)

1. Study Overview

This study is a cross-sectional imaging study designed to evaluate inter-observer reliability of radiographic measurements obtained from pelvic and spine radiographs in both standing and sitting positions. Each subject undergoes a one-time visit with acquisition of standardized radiographs. No longitudinal follow-up or intervention is performed.

2. Objectives

- **Primary Objective:**
  To assess inter-observer reliability of three radiographic measurements:
    - Sacral slope
    - Pelvic femoral angle
    - Cup ante-inclination
- **Secondary Objective:**
  To summarize measurement values across observers and positions (standing vs. sitting).

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3. Analysis Population

All subjects who:

- Provide informed consent, and
- Successfully complete radiographic imaging

will be included in the analysis.

No imputation will be performed for missing data. Subjects with incomplete or unreadable radiographs will be excluded from analyses specific to the affected measurement(s).

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4. Data Collection and Structure

- Each radiograph will be:
    - Interpreted clinically by radiology (standard of care)
    - De-identified for study analysis

- Four independent evaluators will measure:
    - Sacral slope
    - Pelvic femoral angle
    - Cup ante-inclination
- Measurements will be obtained for:
    - Standing position
    - Sitting position

Thus, the data will have a **nested/repeated structure**:

- Multiple raters per image
- Two positions per subject

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5. Statistical Methods

5.1 Descriptive Statistics

For each measurement and position:

- Mean and standard error (SE) will be estimated using model-based approaches
- Additional descriptive summaries may include:
    - Median
    - Standard deviation (SD)
    - Range (min, max)

Model-adjusted means will be reported to account for clustering by subject and rater.

5.2 Primary Analysis: Inter-Observer Reliability

Inter-observer reliability will be assessed using **Intraclass Correlation Coefficients (ICC)** derived from **linear mixed-effects models (LMMs)**.

- Separate models will be fit for each measurement:
    - Sacral slope

    - Pelvic femoral angle
    - Cup ante-inclination
- The LMM will include:
    - **Random effects** for subject and rater
    - Position (standing vs. sitting) may be included as a fixed effect if appropriate
- ICC estimates will be calculated from variance components:
    - Between-subject variance
    - Between-rater variance
    - Residual variance
- **95% confidence intervals (CIs)** for ICC values will be reported.

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6. Handling of Multiple Comparisons

Because three primary measurements are being evaluated independently, no formal adjustment for multiple comparisons will be applied. Results will be interpreted in the context of consistency across outcomes rather than strict hypothesis testing.

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7. Significance Level

- A two-sided **alpha level of 0.05** will be used
- Statistical significance will be defined as **$p < 0.05$**, where applicable

Note: Emphasis will be placed on **effect sizes (ICC values) and confidence intervals** rather than p-values alone.

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8. Assumptions and Model Diagnostics

The following assumptions underlying linear mixed-effects models will be assessed:

- **Normality of residuals**
    - Evaluated using Q-Q plots and residual histograms
- **Homoscedasticity (constant variance)**

    - Assessed via residual vs. fitted value plots
- **Independence**
    - Accounted for through appropriate random effects structure

If assumptions are violated:

- Transformations or alternative modeling approaches will be considered
- Sensitivity analyses may be conducted

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9. Software

All statistical analyses will be conducted using:

- **SAS**
- **IBM SPSS Statistics**

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10. Missing Data

- No imputation will be performed
- Analyses will be conducted using available data
- The extent and pattern of missing data will be described

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11. Data Presentation

Results will be presented using:

- Tables of ICC values with 95% CIs
- Summary tables of model-adjusted means and SEs
- Optional graphical displays (e.g., boxplots by rater and position)

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12. Quality Control

- Use of a single radiologic technologist for imaging acquisition to reduce variability
- Standardized measurement definitions for all evaluators

- Independent measurements by four observers to minimize bias