Research

International Journal of Clinical and Medical Case Reports

Reliability Investigation of Radiation Therapists Assessment for Radiation Induced Skin-Toxicity

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Received Date: 24 Jan 2026

Accepted Date: 09 Feb 2026

Published Date: 14 Feb 2026

Citation:

Ramy Abdlaty. Reliability Investigation of Radiation Therapists Assessment for Radiation Induced Skin-Toxicity. International Journal Clinical and Medical Case Reports, 2025; 7: 1-8

1. Abstract

1.1. Purpose: Enhancing the quality of radiotherapy for skin cancer requires systematic evaluation of radiation-induced skin toxicity, particularly acute toxicity, which affects ~90% of patients receiving ionizing radiation. This study assessed the reliability of a newly developed visual grading tool, the Clinician Erythema Assessment–Radiation Therapy (CEA-RT), designed to help radiation clinicians evaluate early radiation dermatitis.

1.2. Methods and Materials: The CEA-RT tool utilizes a 5-point scale. Its reliability was evaluated by analyzing intra-rater and inter-rater agreement among clinicians, as well as its accuracy against a reference standard. The assessment was conducted using digital images.

1.3. Results: The study's results showed high intra-rater reliability, with 98% of scores falling within ±1 grade and consistent grading for regions of interest (ROI). However, inter-rater agreement was only 60%, indicating variability among different clinicians. Accuracy against a reference standard was moderate, with 25–30% of radiation therapists achieving high concordance and over 50% showing moderate agreement.

1.4. Conclusions: The findings support the CEA-RT scale as a reliable tool for individual use. However, study limitations included variable time gaps between sessions, recall bias, fatigue, and reliance on digital images. The results emphasize the need for additional training, in vivo validation, and inclusion of diverse skin types to improve overall accuracy and applicability.

2. Keywords: Radiation Therapy; Radiation-induced Dermatitis; Skin Toxicity; Erythema; Visual Grading; Ionizing Radiation

3. Introduction

Occupational skin cancers constitute a substantial proportion of all reported occupational diseases [1]. The persistent increase in skin cancer incidence over recent decades has established it as a major global public health priority. Epidemiologically, skin cancer is the most prevalent malignancy globally, representing approximately more than 40 % of all cancer diagnoses [2]. Within the United States, its annual incidence exceeds that of all other cancers combined, incurring estimated treatment costs of $8.1 billion [3]. Solar ultraviolet radiation (UVR) is the paramount risk factor [4]. According to joint estimates by two international organizations such as the World Health Organization (WHO) and the International Labor Organization (ILO), occupational exposure to UVR affects approximately 1.6 billion individuals worldwide, accounting for 28.4% of the global working-age population. [5].

Skin cancer (SC) management employs a range of therapeutic modalities, with surgery and radiotherapy (RT) being the most frequently applied [6]. Surgical intervention is often the primary and preferred treatment when clinically indicated [7]. However, for senior patients, surgery may be ineligible due to comorbidities that pose a life-threatening risk [8] or the potential for a significant negative impact on quality of life [9]. Consequently, a substantial proportion of geriatric SC patients are referred for RT as a prime treatment alternative [10].

Despite its worth, radiotherapy has some limitations, as it can induce a range of adverse effects, most notably radiation-induced skin toxicity [11]. This toxicity is a highly common sequela, affecting approximately 9 out of 10 SC patients undergoing RT treatment [12]. The severity of these reactions exists on a spectrum from mild to severe and typically manifests in a predictable temporal sequence [13]:

i. Primitive Erythema: The most immediate skin reaction is inflammation (erythema), which can arise within hours' post-irradiation. In some cases, however, its onset may be delayed for up to two weeks following the initiation of RT [14]..

ii. Dry and Moist Desquamation: After approximately three weeks of radiation, damage to the basal layer of the epidermis results in painful epidermal necrosis. This clinically presents as desquamation (peeling), which can be either dry or moist (involving serous exudate) [15].

iii. Ischemia and Necrosis: Within three months of treatment initiation, cutaneous ischemia and frank necrosis may occur as a consequence of vascular damage and compromised tissue

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perfusion [16].

iv. Postponed Effects: Delayed and often chronic skin changes, including telangiectasia (dermal capillary dilation), fibrosis, and severe dermal necrosis, can emerge approximately twelve months after irradiation [17].

Accurate and reproducible assessment of these toxicities is critical for optimal patient management. It guides clinical decisions regarding treatment interruptions, supportive care interventions [18], and the evaluation of novel radioprotectant agents [19]. The current standard for grading radiation dermatitis relies on clinician-reported outcome (ClinRO) measures [20], most commonly the Radiation Therapy Oncology Group (RTOG) and the Common Terminology Criteria for Adverse Events (CTCAE) scales [23]. These tools provide a valuable framework for documenting toxicity across a broad range of severities, from erythema to ulceration.

However, a significant methodological gap exists in the assessment of the earliest and most common manifestation: cutaneous erythema. As previously noted, cutaneous erythema is a prevalent sequela of radiation therapy, manifesting as an inflammatory response characterized by a pronounced reddening of the skin [21], [22], [23] as shown in Figure 1. This erythema represents a visible indicator of pathophysiological impairment to the epidermal basal layer, which subsequently triggers a localized vasodilation response, increasing dermal blood flow and volume [24]. While the RTOG and CTCAE scales include erythema, they often categorize it within a single, broadly defined grade (e.g., Grade 1: faint erythema). This lack of granularity can limit sensitivity in detecting subtle, early changes and may compromise inter-rater reliability in clinical trials and practice [25]. Furthermore, these scales are generalized for all anatomic sites and cancer types, and their descriptive anchors may not fully align with the nuanced progression observed in skin cancer radiotherapy [26].

Consequently, while numerous validated visual grading scales exist for radiation-induced dermatitis, the validity and reliability of these instruments for quantifying early-stage radiation-induced skin inflammation remain inadequately explored [17]. This gap underscores the need for a assessment tool that offers greater precision for early erythema while being pragmatically integrated into the radiation oncology workflow.

The primary objective of this study was to systematically evaluate the reliability of a modified clinician erythema assessment tool, adapted for the specific context of radiation oncology. This revised technique, designated the CEA-RT, is a five-level ordinal scale developed to standardize the grading of erythema associated with early radiation dermatitis by clinical practitioners, including radiation therapists and oncologists. A critical refinement of the CEA-RT is its utilization of descriptive terminology that aligns precisely with the specialized lexicon of radiation oncology, thereby enhancing its clinical applicability and face validity within the field as displayed in Figure 1.

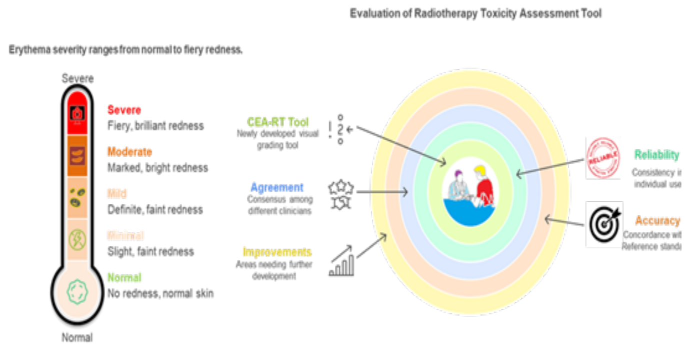

Figure 1: The left panel illustrates the varying symptoms of erythema severity, ranging from faint redness of the skin to intense erythematous reactions of the epidermal tissue. The right panel presents a visual summary of the study, outlining the methodology (development of the CEA-RT tool), key findings (inter-clinician agreement), and the discussion and conclusion (the required improvements to achieve higher reliability and accuracy).

4. Materials and Methods

4.1 Recruitment and Composition of the Radiation Therapist Cohort

For this study, a cohort of twenty radiation therapists was recruited from the JCC (Juravenski Cancer Center, Hamilton, Ontario, Canada). These clinicians brought a substantial breadth of professional experience to the research, with their time in clinical practice ranging widely from 4 to 35 years. This range was intentionally designed to capture perspectives across various career stages. To detail the distribution, the cohort was stratified by years of experience: the largest group, comprising 40% (n=8) of participants, had 4–10 years of practice; 30% (n=6) fell into the 11–20-year range; and the remaining 30% were split evenly, with 15% (n=3) having 21–30 years and 15% (n=3) possessing 31–35 years of clinical experience.

Regarding gender composition, the study cohort consisted of 80% (n=16) female and 20% (n=4) male radiation therapists. This composition provides meaningful context when compared to the broader demographic profile of all radiation therapists employed at the JCC at the time of the study, which totaled 90 individuals. The wider JCC radiation therapists population was 76% female and 24% male, with an even broader spectrum of clinical experience, spanning from 1 to 35 years. This comparison indicates that the study's participant sample was generally reflective of the center's overall gender distribution, while its experience range focused deliberately on more seasoned practitioners, excluding those with less than four years of experience.

4.2 Clinical Procedure and study participants

This single-center study was conducted to evaluate the reliability of the CEA-RT, a five-level visual assessment scale revised for use in radiation therapy, in grading the severity of radiation-induced erythema. All participants provided written informed consent prior to enrollment. The exclusion due to missing photographs was to ensure analysis consistency. Experienced radiation therapists independently applied the CEA-RT technique to grade erythematous

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reaction in digital images obtained from nine patients (aged 56–88 years) treated at the JCC in 2015, 2016, and 2017. One patient was excluded from the analysis due to the unavailability of photographs.

All patients were Caucasian (four males and five female) and had histologically confirmed either early-stage basal cell carcinoma (BCC) or squamous cell carcinoma (SCC) of the skin. Treatments were delivered with curative intent using either electron beams (6–12 MeV) or orthovoltage x-rays (65–130 kVp). None of the patients had received prior radiotherapy to the same anatomical site. The prescribed radiation doses varied between approximately 31 Gy and 50 Gy, delivered over treatment periods of 2, 3, or 4 weeks, with five fractions administered per week. Irradiation was administered to several anatomical sites, including the extremities, cervical region, face, forehead, and pinna. The study protocol was reviewed and approved by the institutional research ethics board.

4.3 Image Acquisition

Digital skin images of Caucasian patients undergoing radiation therapy were obtained from a related consented study. These images, captured using a standardized protocol with a color-calibrated digital camera (HDMI-768, Hyundai, Korea) under consistent lighting, documented the progression of erythema over the course of treatment. Only images meeting clear quality and framing criteria were included. For this study, the images were de-identified and presented in a fully randomized order to reduce potential bias associated with expected erythema progression. This randomization was applied across all patients and timepoints to ensure assessors could not deduce treatment chronology during evaluation.

4.4 Study Design

The study comprised three phases: one training session followed by two independent grading sessions. Training session: participating radiation therapists (RTs) were familiarized with the CEA-RT technique via a structured slide-based presentation covering scale definitions and application rules. Sample images, selected to represent clear examples of each of the five CEA-RT levels and sourced from patients not included in the subsequent grading sets, were exhibited in Figure 2. A collaborative grading exercise using 20 practice images was then conducted, during which participants assigned erythema grades as a group to discuss discrepancies and achieve consensus, ensuring a shared understanding of the scale.

Figure 2: Reference diagram for the Clinician Erythema Assessment for Radiation Therapy (CEA-RT). This tool provides a standardized 5-point ordinal scale and corresponding clinical photographs to aid practitioners in consistently grading the severity of cutaneous erythema resulting from radiotherapy.

Grading sessions: Following training, each RT independently assessed digital images in two separate sessions. The same set of 158 images was presented in an identical, randomized order during both sessions, with a minimum interval of three hours between assessments to reduce recall bias.

Two sets of images were evaluated in each grading session:

i. Field-of-view (FOV) images: 60 images from six patients, each showing the full treatment region. A circular ROI measuring 2 cm in diameter was marked on each image.

ii. ROI-only images: 98 images from nine patients, each displaying only the isolated ROI without the surrounding FOV.

Radiation therapists were directed to confine their erythema assessment solely to the ROI. For FOV images, the irradiated field was outlined, enabling direct side-by-side comparison of irradiated and non-irradiated adjacent skin to support grading accuracy as displayed in Figure 3.

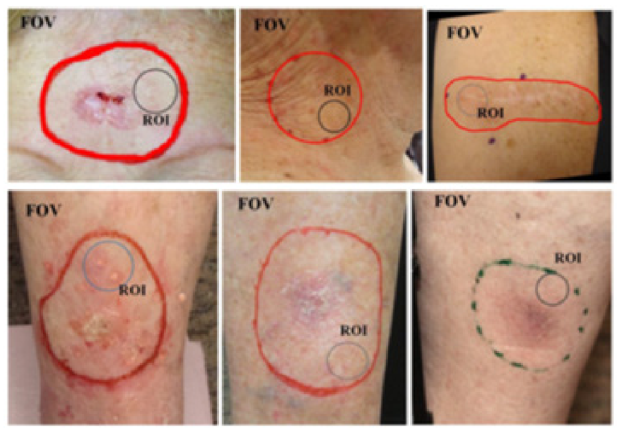

Figure 3: Six sample images are presented, each depicting the full treatment field or FOV. Within each FOV, a 2-cm circular ROI was delineated for erythema grading.

All images were displayed on identical, color-calibrated monitors under controlled, low-ambient lighting conditions. Participant RTs were equipped with the CEA-RT scale reference and a standardized scoring form. Reliability was evaluated by examining both intra-rater (test-retest consistency for each radiation therapist) and inter-rater (agreement among different radiation therapists) variability using weighted Cohen's kappa statistics. Grading accuracy was determined by comparing each radiation therapist's scores, as well as pooled group scores, against a gold standard.

The gold standard was defined as the consensus scores from a panel of three expert assessors, including the study instructor—a senior radiation therapist with extensive expertise—who independently graded all images. This panel's consensus was established prior to the RT grading sessions.

5. Data Analysis

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This study evaluated the consistency and accuracy of radiation therapists' grading of erythema using the CEA-RT scale on two image sets: FOV and ROI. Ordinal data were collected using a five-point severity scale, where 0 indicated normal skin status, 1 minimal erythema, 2 mild erythema, 3 moderate erythema, and 4 severe erythema. Because the scores represent attribute data, statistical analysis was performed using the Attribute Agreement Analysis module in Minitab® 18 Statistical Software. This analysis assessed intra-rater reliability (within rater), inter-rater reliability (between raters), and agreement with a gold standard (accuracy). The following statistical methods were applied:

5.1 Absolute Agreement

Absolute agreement denotes a statistical approach that evaluates the exact concordance between raters, instruments, or methods in their assessment of the same subject or item, emphasizing precise matching rather than mere correlation. It is a fundamental metric in reliability and agreement studies, with critical applications in domains such as clinical research, psychology, and quality control. For our study, each radiation therapist graded all images twice, allowing intra-rater consistency to be quantified as the percentage of identical ratings across both sessions. Agreement was categorized as follows: <50% = poor, 50–70% = good, ≥70% = excellent [27]. This method provides a straightforward measure of inter- or intra-rater reliability by calculating the proportion of cases in which identical scores or classifications are assigned [28]. The computation is defined by the following equation:

$$\text{Absolute Agreement (\%)} = \frac{\text{(Number of exact agreements)} * 100}{\text{(Total number of ratings)}} \qquad \text{Equation 1 [28]}$$

Where:

- Number of exact agreements = the count of items observations where raters provided identical ratings.
- Total number of ratings = the total number of items assessed across raters or sessions

5.2 Fleiss' Kappa (κ)

Fleiss' kappa is a statistical measure of inter-rater agreement for categorical data when there are more than two raters. It extends Cohen's kappa beyond the two-rater case and adjusts for the amount of agreement expected by chance [29]. In our case we have multiple radiation therapists with various years of experience. To evaluate the statistical significance of the inter-rater agreement, Fleiss' kappa was calculated with an alpha level of 0.05. The hypotheses tested were:

H0: Agreement is attributable to chance.

H1: Agreement is greater than chance.

Kappa values range from −1 to +1, where 1 indicates perfect agreement, 0 indicates chance-level agreement, and negative values indicate less-than-chance agreement [30]. For interpretation, the Landis and Koch classification was adopted: <0 = poor; 0–0.20 = slight; 0.21–0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = substantial; 0.81–1.00 = almost perfect.

The formula for Fleiss' kappa is:

$$\kappa = (\bar{P} - \bar{P}_e) / (1 - \bar{P}_e) \qquad \textbf{Equation 2 [30]}$$

Where:

- κ is Fleiss' kappa.
- $\bar{P}$ is the observed proportion of agreement.
- $\bar{P}_e$ is the expected proportion of agreement by chance

5.3 Kendall's Coefficients

Kendall's coefficients are originally non-parametric statistical measures utilized to account for the level of association or the degree of agreement between ordinal data. They are particularly advantageous for analyzing datasets or in research studies where the hypotheses required for parametric correlation methods are not fulfilled [31]. To account for the ordinal nature of the data, Kendall's coefficient of concordance (W) and Kendall's correlation coefficient (τ) were calculated. These tests assess the degree of association among ratings, with greater penalties assigned to misclassifications differing by more than one category compared to adjacent-category errors.

Kendall's coefficients range from −1 (perfect negative association) to +1 (perfect positive association). For this study, <0.70 = low, 0.70–0.80 = medium, 0.80–0.90 = high, and 0.90–1.00 = very high association [32]. The hypotheses were:

H0: No association exists among ratings.

H1: Ratings are associated (i.e., agreement is not due to chance).

Significance was determined at $\alpha = 0.05$. Kendall's coefficients (W) is computed as shown:

$$W = (12 * S) / (k^2 * N * (N^2 - 1)) \qquad \textbf{Equation 3 [32]}$$

Where:

- **S** is the sum of squared deviations of the rank sums.
  - First, sum the ranks given by all raters for each subject (patient) to get R_i.
  - Find the mean of these rank sums, $\bar{R}$.
  - $S = \Sigma(R_i - \bar{R})^2$
- **k** is the number of raters (e.g., radiation therapists).
- **N** is the number of subjects (e.g., patients being ranked).

5.4 Attribute Data Considerations

In health preference research (HPR), the identification of attributes and levels may be achieved through exploratory approaches or elicitation techniques, with triangulation of methods recommended to enhance validity. Attributes should be clearly defined and supported with concise descriptions and appropriate visual aids to minimize potential bias. A systematic deconstruction of decision models into attributes and levels is essential to ensure the validity, reliability, and objectivity of HPR study designs. To safeguard validity in the present study, images were evaluated in random order to mitigate sequence bias. Consistent with established standards for attribute agreement testing [33], at least 50 samples covering the full range of process variation were included, each evaluated twice by multiple appraisers (minimum 3–5 clinicians).

6. Results & Discussion

6.1 Radiation Therapists' Absolute Agreement

Intra-rater reliability was assessed for each participating radiation therapist. The percentage of perfect (100%) attribute agreement between the assessment sessions ranged from 45% to 85% for full-FOV images and from 47% to 88% for region-of-interest

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(ROI) images. A majority of radiation therapists demonstrated a consistency rate of 45–75% across both image types. When evaluated against a strict match criterion, both FOV and ROI image sets yielded equivalent agreement results. Radiation therapists were categorized based on their agreement rates: 35% (n=7) exhibited excellent agreement (≥70% match), 50% (n=10) demonstrated good agreement (50–69% match), and 15% (n=3) showed poor agreement (<50% match). Overall, 85% of radiation therapists achieved good or excellent intra-rater reliability as illustrated in Figure 4.

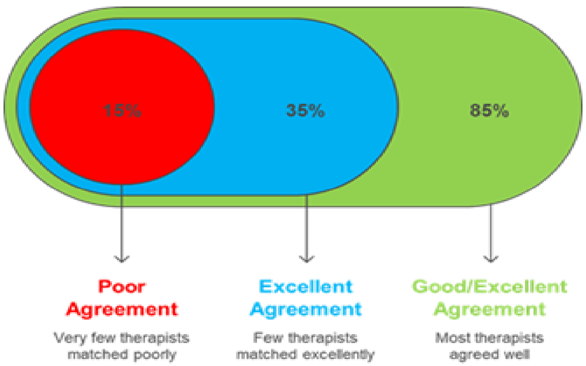

Figure 4: A comparison of intra-rater reliability scores among radiation therapists for assessing radiation-induced erythema using ROI and Full-FOV images. Based on intra-rater agreement rates, radiation therapists were categorized as exhibiting excellent (35%; n=7), good (50%; n=10), or poor (15%; n=3) reliability, with 85% overall achieving good-to-excellent consistency.

6.2 Radiation Therapists' Kappa test

To quantify inter-rater agreement, Fleiss' kappa was calculated, and its statistical significance was evaluated. Applying the Landis and Koch criteria for interpretation, the analysis revealed a range of kappa values from 0.21 to 0.78 for full-FOV images and 0.26 to 0.83 for region-of-interest (ROI) images, with all results being statistically significant ($p < 0.01$). Overall, agreement was stronger for ROI images, with 85% of radiation therapists demonstrating moderate or better self-agreement, compared to 60% for FOV images. Substantial or almost perfect agreement was uncommon, observed in a minority of cases. An illustration of kappa test is shown in Figure 5.

Figure 5: Fleiss' kappa analysis demonstrated statistically significant inter-rater agreement for both FOV (κ = 0.21–0.78) and ROI (κ = 0.26–0.83) images ($p < 0.01$). Agreement was generally stronger for ROI images, where 85% of radiation therapists achieved moderate or better self-consistency compared to 60% for FOV images

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6.3 Radiation Therapists' Kendall's coefficients

To evaluate agreement while accommodating the ordinal characteristics of the data, Kendall's correlation coefficient (KCC) was employed. Intra-rater reliability analysis demonstrated strong correlations, with KCC values ranging from 0.82 to 0.96 for FOV images ($p \leq 0.0015$) and from 0.76 to 0.97 for ROI images ($p \leq 0.0007$). High correlation ($0.80 \leq KCC < 0.90$) was observed among 80% (16/20) of radiation therapists for FOV images and 10% (2/20) for ROI images, while very high correlation ($0.90 \leq KCC \leq 1.0$) was found in 20% (4/20) and 85% (17/20) of radiation therapists, respectively. Overall, all FOV images (100%) and the majority of ROI images (95%) demonstrated statistically significant high or very high intra-rater correlation. The results of Kendall's coefficients are visually displayed in Figure 6.

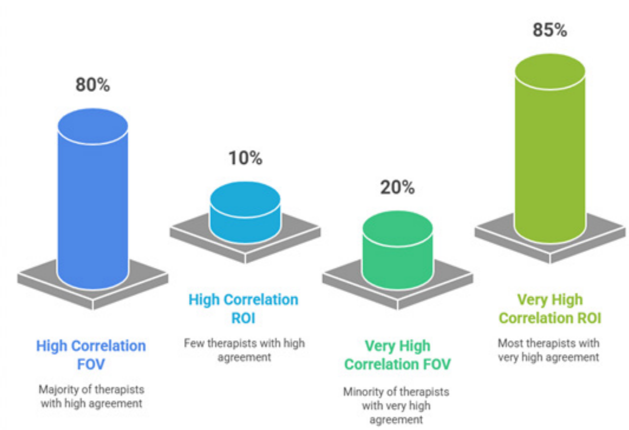

Figure 6: Kendall's correlation coefficient was used to evaluate intra-rater agreement for ordinal-scale data. Strong and statistically significant correlations were found for both FOV (KCC = 0.82–0.96, $p \leq 0.0015$) and ROI images (KCC = 0.76–0.97, $p \leq 0.0007$). Very high agreement ($KCC \geq 0.90$) was observed in 85% of radiation therapists for ROI images, compared to 20% for FOV images; overall, 95% of ROI and 100% of FOV ratings showed high or very high agreement.

6.4 Radiation Therapists Attribute Data considerations

The concordance between each radiation therapist's ratings and the reference standard was evaluated using 100% agreement analysis. As illustrated in Figure 7, the 95% confidence intervals revealed that most radiation therapists provided correct ratings in 20–65% of cases. Agreement with the standard ranged from 13% to 85% for FOV images and from 10% to 88% for ROI images. Radiation therapists were subsequently grouped into performance categories: less than 50% agreement was classified as low, 50–80% as good, and greater than 80% as excellent. For FOV images, 70% (14/20) of radiation therapists demonstrated low agreement, 25% (5/20) achieved good agreement, and 5% (1/20) attained excellent agreement. The results were similar for ROI images, with 75% (15/20) showing low agreement, 20% (4/20) good, and 5% (1/20) excellent. Overall, 70-75% of radiation therapists demonstrated low agreement with the standard, while 25-30% demonstrated good to excellent agreement.

6.5 Study Limitations

The study findings are constrained by several key methodological and demographic limitations. The reliance on digital photographs without standardized color-calibration during capture or review may introduce technical variability influencing grading. Methodologically, the use of a single-expert gold standard may introduce bias, and presenting images in the same order across sessions, while controlling for sequence, may have reduced the effectiveness of the test-retest interval. Furthermore, the analysis did not account for the clustering of multiple images per patient, which could affect statistical independence. As a single-center study with a sample limited exclusively to Caucasian skin tones, the results lack generalizability to diverse populations and clinical settings. In darker skin tones, where erythema is more challenging to assess visually, scale performance may differ substantially. The initial training, while necessary, may also have inadvertently anchored graders to specific examples. Therefore, while radiation therapists demonstrated good intra-rater reliability, accuracy against the benchmark was only moderate. Future work requires in vivo validation, a diverse multi-center population, and advanced training to improve concordance.

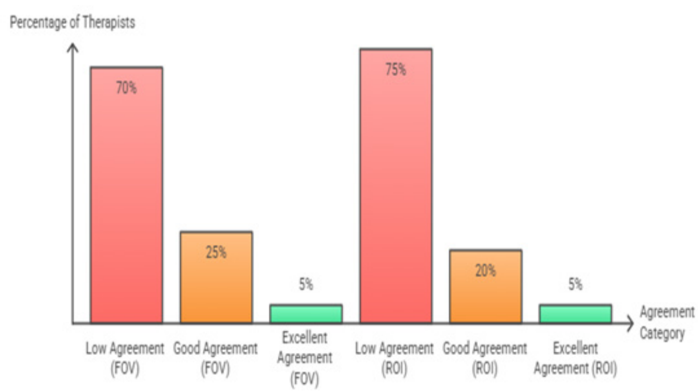

Figure 7: Agreement between radiation therapists' ratings and the standard ranged from 13–85% for FOV images and 10–88% for ROI images. Overall, 70–75% of radiation therapists demonstrated low agreement (<50%), while only 25–30% achieved good (50–80%) or excellent (>80%) agreement.

7. Conclusions

In conclusion, the evaluation of the CEA-RT scale revealed a distinct disparity between its reliability and its accuracy. Intra-rater reliability was strong, with 85% of radiation therapists achieving "good" or better self-agreement (weighted $\kappa \geq 0.61$) and grade differences within ±1 for ≥98% of images. However, inter-rater reliability was markedly lower, with Fleiss' κ indicating only overall "fair" agreement ($\kappa = 0.28$; 95% CI: 0.24–0.32) among all radiation therapists. When evaluated against a reference standard, the overall accuracy was moderate, with an exact agreement of 58.2% and a weighted κ of 0.52 against the expert consensus. Concordance with the standard was statistically significant and moderate or better for 50–60% of radiation therapists; however, only 25–30% demonstrated good to excellent agreement (weighted $\kappa > 0.60$). This indicates that while a majority of assessments were satisfactory, a substantial proportion failed to achieve a high degree of fidelity to the benchmark.

Clinical Impact: The strong intra-rater reliability suggests the scale is well-suited for longitudinal tracking by a single therapist, a common clinical scenario. However, the lower inter-rater agreement highlights a challenge for multi-clinician trials or audits, where standardized training is crucial. The moderate accuracy against an expert benchmark confirms its utility as a clinical tool but indicates it should be complemented with expert review for high-stakes decisions.

These findings are constrained by limitations, including the use of digital photographs from a single cohort of nine patients—which may introduce technical variability—and a sample limited to Caucasian skin tones, affecting generalizability. Therefore, while radiation therapists can apply the CEA-RT scale consistently with themselves, its accuracy for objective measurement is moderate. Future validation should involve in vivo studies with a diverse patient population and consider supplemental training to improve concordance.

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