



Research Article

Enhancing Pseudarthrosis Diagnosis: Dynamic Radiographs After Cervical Fusion with Stand-Alone Intervertebral Cage

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Abstract

Background: Pseudoarthrosis, a potential complication of cervical fusion, necessitates accurate diagnostic methods. This study evaluates the efficacy of dynamic radiographs in detecting pseudoarthrosis after Anterior Cervical Discectomy and Fusion (ACDF) using self-locking stand-alone intervertebral cages for treating Cervical Degenerative Disease (CDD).

Methods: Retrospective analysis of radiological data from 47 patients (84 levels) who underwent 1- to 3-level ACDF with a minimum 24-month follow-up was conducted. Pseudoarthrosis was diagnosed via Computed Tomography (CT) by a blinded neuroradiologist. Two independent neurosurgeons measured Cobb angles in dynamic radiographs, correlating them with CT for pseudoarthrosis detection. The Intraclass Correlation Coefficient (ICC) assessed dynamic radiograph evaluator agreement, while ROC curves compared Cobb angle accuracy.

Results: Excellent evaluator agreement was found in dynamic radiograph Cobb angle measurements (ICC = 0.993). Comparing Cobb angles between CT-diagnosed levels with and without pseudoarthrosis revealed a median of 6.3° for levels without fusion. A Cobb angle $\geq 5^\circ$ exhibited higher specificity (85.9%), positive predictive value (47.4%) and accuracy (AUC = 0.762) than smaller angles (1°, 2°, 3° and 4°).

Conclusion: In patients with Cervical Degenerative Disease (CDD) undergoing Anterior Cervical Discectomy and Fusion (ACDF) with self-locking stand-alone intervertebral cages, a Cobb angle change of $\geq 5^\circ$ on dynamic radiographs appears to be a reliable threshold for predicting pseudoarthrosis. These findings support using this simple, non-invasive and cost-effective method as a valuable adjunct in diagnosing suspected pseudoarthrosis, contributing to improved clinical decision-making in postoperative cervical fusion management.

Keywords: Cervical Degenerative Disease; Pseudoarthrosis; Anterior Cervical Discectomy and Fusion; Dynamic Radiographs; Intervertebral Cages; Diagnostic Accuracy

Abbreviations

ACDF: Anterior Cervical Discectomy and Fusion; AUC: Area Under the Curve; CT: Computed Tomography; CDDD: Cervical Degenerative Disc Disease; HA: Hydroxyapatite; NPV: Negative Predictive Value; PPV: Positive Predictive Value; ROC: Receiver Operating Characteristic

Introduction

Cervical Degenerative Disease (CDD) characterizes the age-related deterioration of intervertebral discs leading to clinical manifestations like neck pain, stiffness, persistent discomfort and conditions such as cervical radiculopathy and myelopathy [1-19]. Among the array of treatment options, the Anterior Cervical Discectomy and Fusion (ACDF) is the most prevalent procedure for addressing CDD [20-34]. ACDF boasts high fusion rates; nonetheless, about 5.8% of patients face fusion failure, termed pseudoarthrosis, after ACDF, exposing them to potential postoperative complications like chronic neck pain [7,21].

The realm of pseudoarthrosis risk encompasses acknowledged surgical factors like multilevel fusions, choice of instrumentation and interbody grafts. Adding to the complexity are patient-related factors such as smoking, obesity, diabetes and age, which contribute to escalated complication risks [16,22]. Crucially, the duration of follow-up plays a pivotal role in pseudarthrosis diagnosis. The probability of diagnosis decreases by 48% when the follow-up period is between 6 and 12 months, while studies with longer follow-up, between 12 and 24 months post-ACDF, report significantly higher rates of pseudarthrosis [16].

Diagnosing pseudoarthrosis hinges on radiological data, clinical symptoms or surgical revision. While surgical exploration offers the most accurate fusion status verification, its invasiveness and practicality hinder its application, particularly when numerous patients remain asymptomatic. In this context, CT scans have emerged as the gold standard for radiological diagnosis due to their ability to visualize bone bridges [4,28]. Another diagnostic approach, flexion-extension dynamic radiography, has gained traction, with recent systematic reviews highlighting cervical spine radiographs as the prevalent method for confirming fusion post-ACDF. The popularity of this method stems from its cost-effectiveness, accessibility and limited radiation exposure [23].

Although some experts have argued in favor of spinous process measurements over the Cobb angle for greater accuracy, this method faces criticism due to the absence of a standardized measurement scale or reliable bone structure reference. Moreover, no consensus exists regarding the acceptable degree of residual movement to detect cervical fusion on dynamic lateral radiographs, with Cobb angle measurements varying from 1° to 5° [18,23,27].

Against this backdrop, our study aims to assess the precision of Cobb angle measurements in dynamic radiographs of fused levels for pseudarthrosis diagnosis after ACDF for CDD, with CT scans as the benchmark for comparison.

Methods

Study Population

This sub-analysis is part of a cross-sectional analytical study that focused on a case series comprising 49 patients diagnosed with symptomatic Cervical Degenerative Disease (CDD) who underwent Anterior Cervical Discectomy and Fusion (ACDF) surgery between January 2012 and December 2017. The clinical outcomes of this patient cohort were detailed in a previously published report [17]. Radiograph and CT imaging analysis were conducted on a subset of 47 patients, as two patients were excluded due to early development of pseudoarthrosis necessitating reoperation before imaging procedures could be carried out. The flowchart illustrating the patient selection process can be found in Fig. 1.

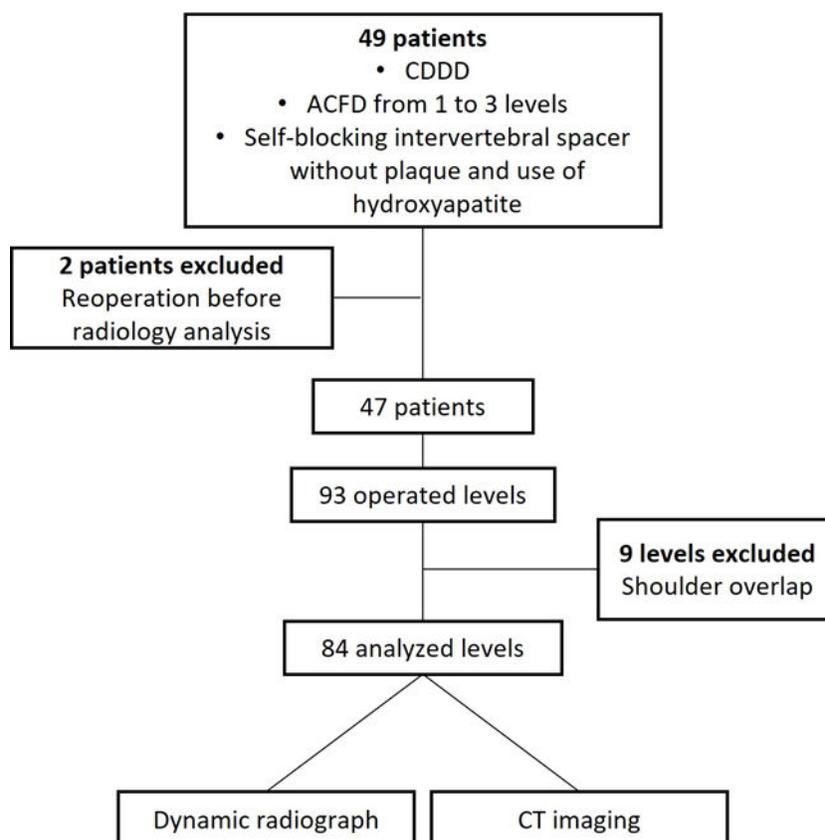


Figure 1: Flowchart of selected levels for pseudoarthrosis analysis.

Inclusion criteria encompassed patients with CDD who had received ACDF surgery by a singular surgeon, spanning 1 to 3 levels, utilizing a self-locking intervertebral spacer sans plate and employing Hydroxyapatite (HA) as the interbody graft material. A minimum follow-up period of 24 months and routine radiological assessments were prerequisites for inclusion. Exclusion criteria encompassed patients with prior cervical arthrodesis, those who had undergone alternate surgical treatments for CDD (such as posterior supplementation techniques or decompression), individuals who had undergone ACDF using cervical plates or non-self-blocking spacer systems, patients subjected to hybrid techniques combined with arthroplasty or those who had undergone ACDF with an auto locking system using interbody graft materials other than HA. Patients possessing incomplete or insufficient medical record data were also excluded from the study. Institutional review board approval was obtained from both Unicamp (Approval No. 3.328.225) and AACD Hospital [Associação de Assistência à Criança Deficiente] (Approval No. 3.353.036) before the commencement of the study.

Radiological Assessment

A suite of anteroposterior, lateral and flexion-extension cervical radiographs was obtained from all patients before surgery and subsequently during follow-up periods, with a frequency of every three months during the first year, every six months during the second year and annually thereafter. Detection of pseudoarthrosis in radiographs was predicated on changes in the Cobb angle across the operated levels. As the gold standard for fusion evaluation, CT scans (axial, coronal and sagittal) were conducted after the patient follow-up period, spanning 24 to 60 months for each individual. Criteria for CT scan evaluation consisted of (1) the presence of trabecular bone bridging at the fused level and (2) the absence of lucent lines at the interbody graft-vertebral body junction. A neuroradiologist, unaware of patients' clinical data, evaluated all scans for fusion status, while two independent neurosurgeons, also blinded to patient clinical data, evaluated Cobb angles on dynamic radiographs. For example, to measure the angle of segment C5-6 in the case below, we use a straight line parallel to the lower plate of C6 and the upper plate of C5. In cases of small angles, we need to draw a parallel line (in red dotted line) to calculate the angle between the two plates. Horos™ (Horos Project), a free and open-source medical image viewer, was used to measure the angles. The difference between the angles in cervical flexion and extension is obtained by simply subtracting both (Fig. 2).

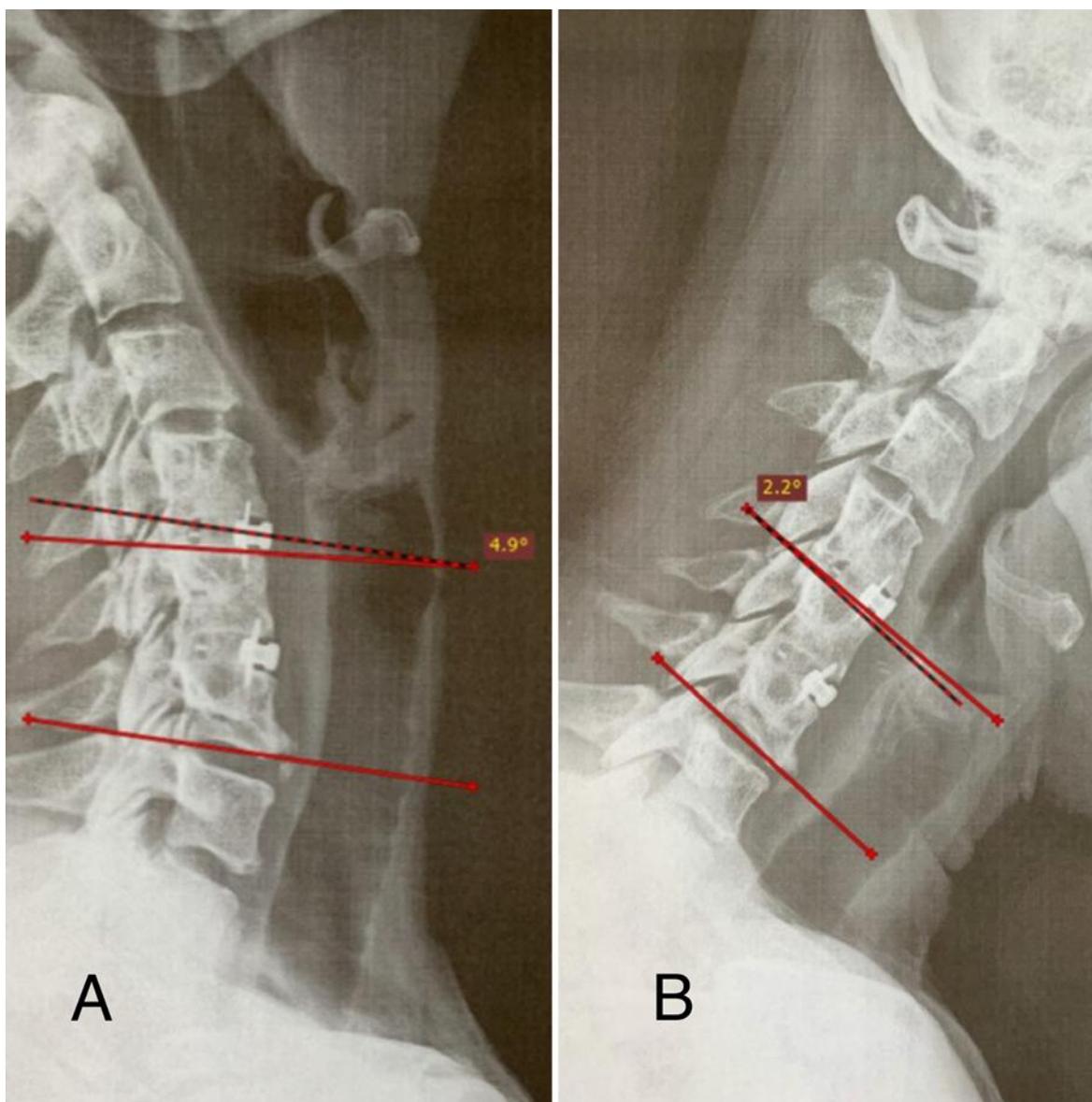


Figure 2: Demonstration of the Cobb angle measurement method on lateral cervical radiographs in flexion and extension.

Statistical Analysis

To determine the level of agreement between Cobb angles assessed by the independent evaluators, the Intraclass Correlation Coefficient (ICC) was employed. The ICC values range from 0 to 1, where 0 indicates lack of agreement and 1 indicates complete agreement between evaluators [20]. For subsequent analyses, the mean of the Cobb angles measured by the two neurosurgeons was utilized. The performance and accuracy of different Cobb angles on dynamic radiographs in comparison to CT scans were assessed using 2x2 tables and the Area Under the Curve (AUC) of the Receiver Operating Characteristic (ROC) curve was calculated. Due to the non-normal distribution of Cobb angle data measured on flexion-extension radiographs (confirmed by Kolmogorov-Smirnov analysis), non-parametric tests (Mann-Whitney, Wilcoxon and Kruskal-Wallis) were employed to compare Cobb angles between cases of pseudoarthrosis (yes and no). Data analysis was carried out using IBM SPSS version 20.0 and statistical significance was defined as $p \leq 0.05$.

Results

Study Population

Initially, the medical records of 49 patients with Cervical Degenerative Disc Disease (CDDD) who underwent 1- to 3-level Anterior Cervical Discectomy and Fusion (ACDF) using self-locking stand-alone cervical cages with Hydroxyapatite (HA) grafts and without plates were scrutinized. The incidence of pseudoarthrosis and clinical improvements in this patient cohort were

previously reported by our group. Among the 98 operated levels from these 49 patients, a fusion rate of 83.6% (82/98) and a pseudoarthrosis rate of 16.4% (16/98) were noted [17].

For the correlation analysis, two out of the initial 49 patients were excluded. These patients necessitated reoperation due to pseudoarthrosis before radiological assessment: one was reoperated with a cage and plate, while the other underwent reoperation through a posterior approach. This left a total of 47 patients eligible for inclusion in this analysis, among whom 22 had undergone 2-level ACDF procedures (Table 1). The most frequently operated level was C5-6-7, accounting for 93 operated levels. Details of the frequency of all operated levels can be found in Table 2. Among the patients, 9 were diagnosed with asymptomatic pseudoarthrosis, 1 with symptomatic pseudoarthrosis and 37 exhibited fusion. Notably, the patient with symptomatic pseudoarthrosis had undergone 2-level ACDF (C4-5 and C5-6). Successful fusion was observed at the C5-6 level, with a calculated Cobb angle of 3.5°. Pseudoarthrosis occurred at the C4-5 level, with a calculated Cobb angle of 5°.

Number of Operated Levels	Total of Patients (%)	Total of Operated Levels
1	13 (27.7)	13
2	22 (46.8)	44
3	12 (25.5)	36
Total	47 (100)	93

Table 1: Total number of patients by operated levels.

Operated Segments	Total of Patients (%)
C4-5-6-7	9 (19.1)
C4-5	1 (2.1)
C5-6-7	11 (23.4)
C6-7	6 (12.8)
C3-4-5-6	2 (4.3)
C4-5-6	9 (19.1)
C5-6	6 (12.8)
C6-7-T1	1 (2.1)
C5-6-7-T1	1 (2.1)
C3-4, C5-6	1 (2.1)
Total	47 (100)

Table 2: Total number of patients by operated segments.

Radiological Outcomes

A correlation analysis between the CT imaging method and the Cobb angle variation observed in dynamic radiographs was conducted to evaluate fusion after ACDF. Both dynamic radiographs and CT scans were obtained at the patient's last follow-up visits, with a minimum follow-up period of 2 years. A specialized radiologist evaluated the CT images, while two independent neurosurgeons assessed the radiographs. Out of the 93 operated levels, 9 (9.6%) levels could not be analyzed on dynamic radiographs due to shoulder overlap (Fig. 3). Cobb angle analysis was possible for segments C3-4 and C4-5 in all patients. However, for segment C5-6, Cobb angle measurement was infeasible for 2 patients (4.25%), while for segments C6-7 and C7-T1, Cobb angle assessment was not possible for 11 patients (23.4%) and 35 patients (74.4%), respectively.

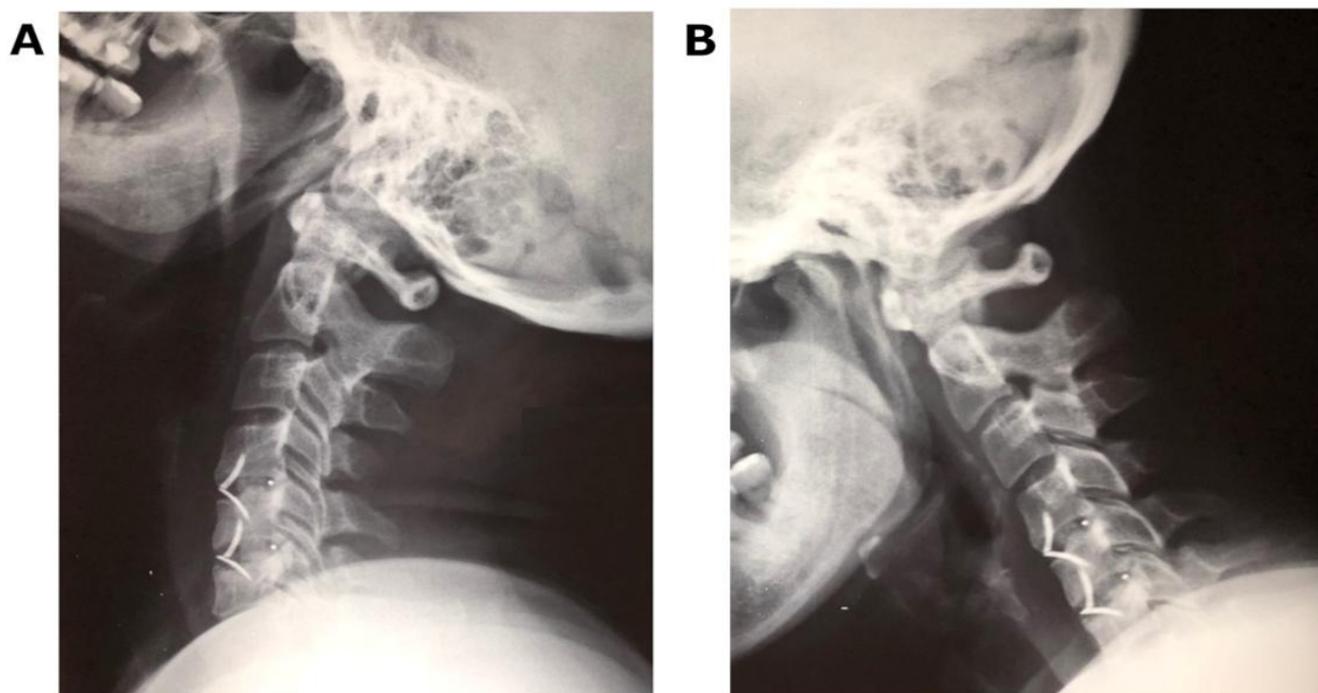


Figure 3: Dynamic radiography in the extension (A) and flexion (B) positions illustrates the overlapping of the shoulders in segments C6-C7. Images from a 43-year-old woman with myelopathy who underwent 3-level ACDF with ROI-C stand-alone cages filled with HA at C4-5, C5-6.

Consequently, the correlation between CT and dynamic radiographs was established for 84 levels (Fig. 4). According to CT analysis, a fusion rate of 84.5% (71/84) and a pseudoarthrosis rate of 15.5% (13/84) were observed for the analyzed levels. The independent evaluations of Cobb angles in dynamic radiographs demonstrated excellent agreement (ICC = 0.993) between the two evaluators ($p < 0.005$), as depicted in Fig.5. By measuring the Cobb angle in dynamic radiographs and comparing it with the presence or absence of pseudoarthrosis in CT scans, a non-fusion status in CT scans corresponded to a Cobb angle of 6.3° . The difference in Cobb angle medians between operated levels with and without pseudoarthrosis was statistically significant ($p = 0.001$), as shown in Fig. 6. This suggests a high cut-off value for the Cobb angle in diagnosing pseudoarthrosis on dynamic radiographs.



Figure 4: Analysis of radiography and computed tomography, both consistent with fusion status.

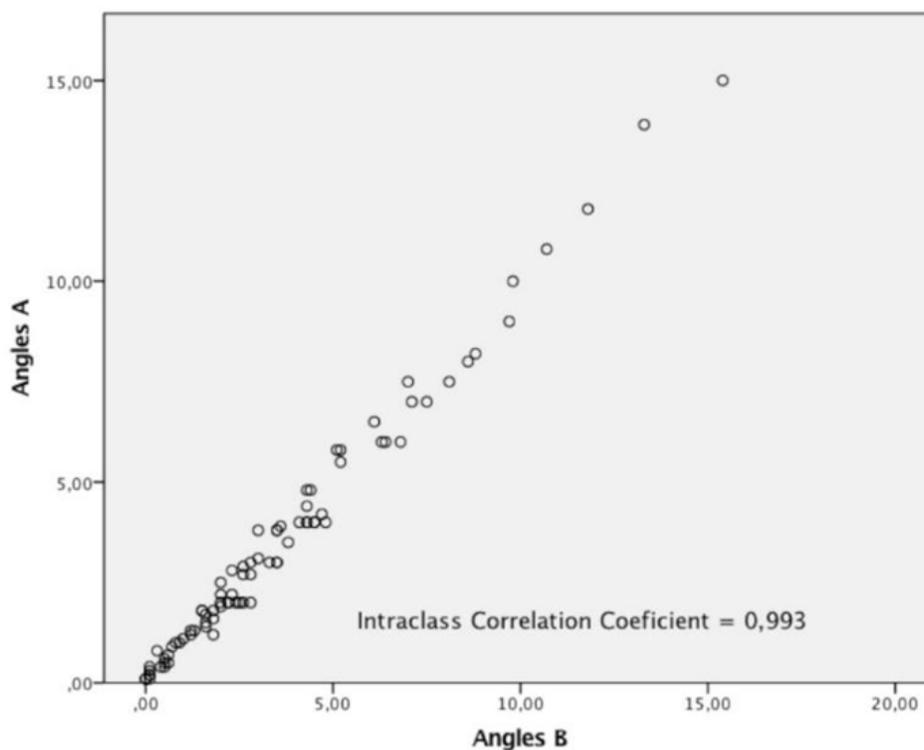


Figure 5: Correlation between independent evaluators (A and B) of dynamic radiographs to determine the Cobb angle in all operated segments. The correlation between the evaluators was calculated by the Intraclass Correlation Coefficient. $p < 0.005$.

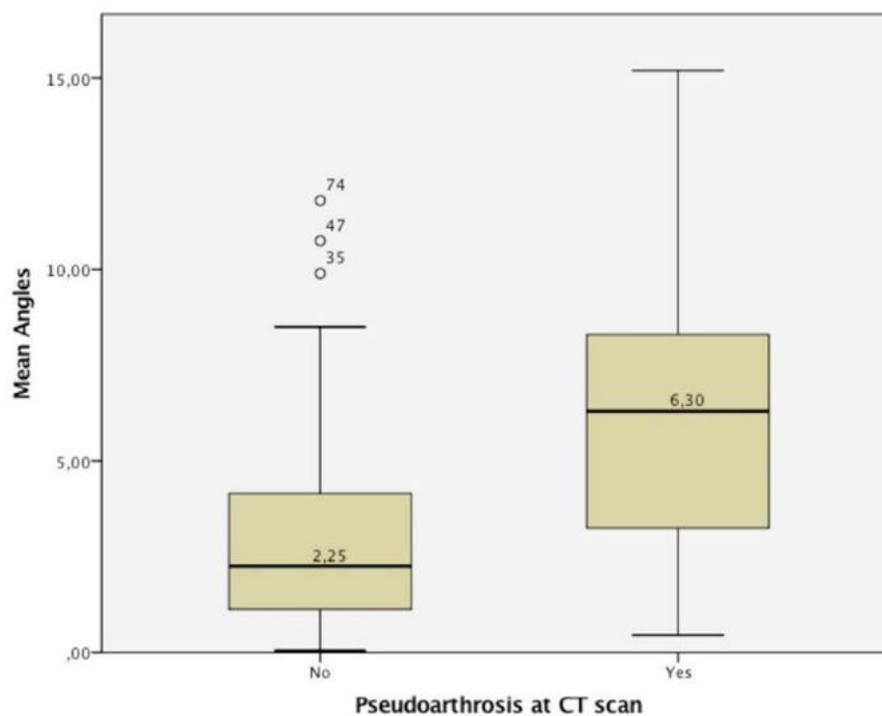


Figure 6: Comparison of the medians of Cobb angle measurement in dynamic radiograph, with the presence or absence of pseudoarthrosis according to computed tomography (CT). $p = 0.001$.

The correlation analysis between the two methods (Table 3) revealed that the Negative Predictive Value (NPV) for different Cobb angle measurements was consistent. While angles $\geq 1^\circ$ and $\geq 2^\circ$ exhibited high sensitivity, they displayed decreased specificity and Positive Predictive Value (PPV). Analyzing angles $\geq 5^\circ$ and $\geq 4^\circ$, comparable sensitivity was observed, yet the Cobb angle $\geq 5^\circ$ exhibited higher specificity (85.9% vs. 71.8%). The PPV for Cobb angle $\geq 5^\circ$ was 47.4%, contrasting with 31% for Cobb angle $\geq 4^\circ$.

	Sensitivity	Specificity	PPV*	NPV#
Cobb $\geq 1^\circ$	92.30%	23.90%	18.20%	94.40%
Cobb $\geq 2^\circ$	92.30%	43.70%	23.10%	96.90%
Cobb $\geq 3^\circ$	76.90%	60.60%	26.10%	93.50%
Cobb $\geq 4^\circ$	69.20%	71.80%	31.00%	92.70%
Cobb $\geq 5^\circ$	69.20%	85.90%	47.40%	93.80%

*PPV: Positive Predictive Value; #NPV: Negative Predictive Value

Table 3: Accuracy table for Cobb angle $\geq 1^\circ$, $\geq 2^\circ$, $\geq 3^\circ$, $\geq 4^\circ$ and $\geq 5^\circ$ related to CT diagnostic method.

The comparison of accuracy between different Cobb angles was evaluated via the ROC curve (Fig. 7). This analysis demonstrated that a Cobb angle $\geq 5^\circ$ had superior accuracy (AUC = 0.762) compared to other angles evaluated, including 1° , 2° , 3° and 4° (Table 4). These findings collectively suggest a higher likelihood of diagnosing pseudoarthrosis using a Cobb angle threshold of $\geq 5^\circ$.

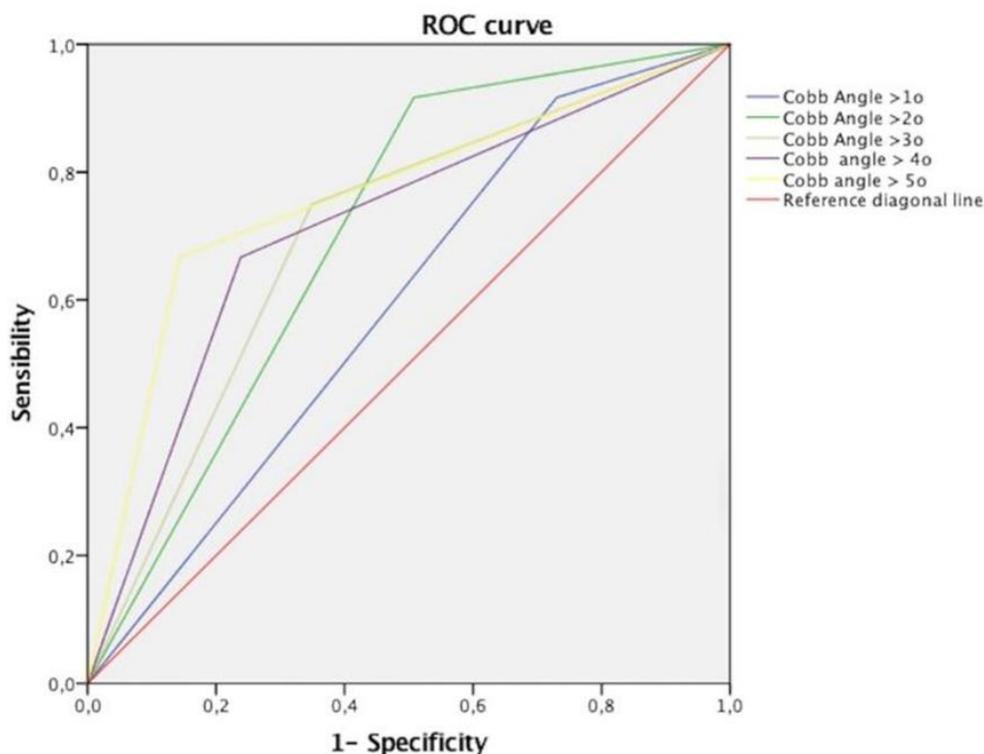


Figure 7: Comparison of the sensitivity and specificity of Cobb angle $\geq 1^\circ$, 2° , 3° , 4° and 5° as a cutoff value for the diagnosis of pseudoarthrosis.

Angle	$\geq 1^\circ$	$\geq 2^\circ$	$\geq 3^\circ$	$\geq 4^\circ$	$\geq 5^\circ$
AUC	0.593	0.704	0.7	0.714	0.762

Table 4: Area under the curve (AUC) for Cobb angles $\geq 1^\circ$, $\geq 2^\circ$, $\geq 3^\circ$, $\geq 4^\circ$ and $\geq 5^\circ$.

Discussion

The accuracy of diagnostic methods for pseudoarthrosis is a critical concern. Radiological techniques play a pivotal role in confirming fusion, providing a non-invasive alternative to surgical exploration. However, the precision and reliability of existing imaging approaches are subjects of ongoing scrutiny. Agreement on optimal criteria for evaluating radiographs to ascertain postoperative fusion remains elusive [8,23,29]. Computed Tomography (CT) has been considered the gold standard for fusion assessment, providing reliable results and it was employed as a reference in this study [4,18,36]. Yet, CT's limited practicality for routine clinical use, due to expense and availability constraints, remains a challenge [12]. Dynamic extension-flexion radiographs offer a more accessible way to assess fusion by evaluating intervertebral motion though questions about their accuracy remain [3,13,31].

Measuring the gap between spinous processes in dynamic radiographs offers an alternative to CT for assessing post-ACDF fusion [23,31]. However, this method relies on measurement scales that aren't always visible, rendering it less practical. Moreover, this approach's accuracy can be compromised by elastic deformations of the spinous process after fusion, leading to overestimation of intervertebral motion by up to 1 mm [8,14,26]. A more reliable approach might involve a scale-independent evaluation of the relationship between spinous processes in flexion and extension radiographs. Consequently, Cobb angle measurement, widely used in fusion status assessment becomes an appealing option [1,2,8,13-15,26,37].

However, the Cobb angle method has its limitations. Not all levels are amenable to dynamic radiograph assessment due to shoulder overlap. For instance, this study found that Cobb angle assessment was impossible for segments C6-7 and C7-T1 in 23.4% and 74.4% of patients, respectively, due to shoulder interference, suggesting CT's superiority in such cases. Moreover, voluntary patient effort during dynamic radiographs can introduce measurement errors by influencing mobility [8]. This issue can be mitigated with software solutions analyzing intervertebral movement in flexion/extension films [10,14,23].

This study primarily adopted the Cobb angle measurement method, which varies widely in literature with thresholds from 1° to 5° [1,2,10,13,24,32,37]. This diversity poses challenges in reaching a consensus, often exacerbated by an absence of clear rationales behind chosen Cobb angle thresholds.

Prior research delved into the sensitivity and specificity of Cobb angle thresholds. Cannada, et al., demonstrated that Cobb angle changes below 2° yielded 82% sensitivity and 39% specificity, substantially improving at a 4° change with 100% specificity [5]. Similarly, Ghiselli, et al., reported 100% specificity and Positive Predictive Value (PPV) for both 1° and 4° Cobb angle changes in pseudoarthrosis assessment. While smaller Cobb angles like 1°, 2° and 3° yielded greater sensitivity in this study, a Cobb angle threshold of $\geq 5^\circ$ demonstrated greater accuracy in diagnosing pseudoarthrosis on dynamic radiographs. This threshold was shown to be robust even in symptomatic patients, where a 5° Cobb angle indicated pseudoarthrosis and a 3.5° Cobb angle indicated fusion. Furthermore, the median Cobb angle in patients diagnosed with fusion through CT was 2.25°, suggesting minimal motion in operated segments in dynamic radiographs of patients without pseudoarthrosis.

Several factors, including individual attributes and surgical instrumentation, can influence patient mobility, potentially affecting the choice of Cobb angle threshold for pseudoarthrosis diagnosis. Mobility is lower in older individuals and those less active, while younger patients often have higher pseudoarthrosis rates due to elevated physical demands and expectations [30]. Surgical instrumentation, like plate usage for fixation, can influence postoperative mobility and fusion rates [11,33].

Taking together, our findings strongly indicate that a Cobb angle variation of 4° or less might yield excessive false positives for pseudoarthrosis diagnosis. A Cobb angle $\geq 5^\circ$ across operated levels in dynamic radiographs appears to be a more robust threshold for predicting pseudoarthrosis after ACDF using self-locking stand-alone intervertebral cages without plates. Importantly, lower cervical levels might necessitate CT due to poor image quality resulting from shoulder overlap in flexion-extension exams.

While this study has limitations such as a small sample size from a single center and a single radiologist's analysis of CT, it's worth noting that interobserver agreement for fusion status assessment via CT scans tends to be high [4]. Furthermore, the study cohort exclusively underwent ACDF with self-locking stand-alone cages without plates, necessitating further study to apply the suggested Cobb angle threshold to patients receiving ACDF with plates.

Although the precise measurement of angular values may present some challenges, interobserver agreement among radiologists was found to be relatively high. The interspinous distance, another radiographic criterion commonly used, requires a reference scale for accurate comparison, which is not always reliable or consistently applied. Additionally, computed tomography while more precise-entails higher costs and exposes patients to greater radiation doses [31-38].

Lastly, the assessment of pseudoarthrosis in lower cervical levels may be limited due to poor image quality in flexion-extension radiographs, caused by the overlapping of the shoulders.

Conclusion

This study highlights the superior diagnostic accuracy of Cobb angle measurements, specifically a threshold of $\geq 5^\circ$, in detecting pseudoarthrosis after ACDF with self-locking stand-alone cages. While smaller Cobb angle thresholds provide higher sensitivity, they may lead to excessive false positives. Our findings underscore the reliability of dynamic radiographs as a diagnostic tool, particularly at higher cervical levels, although lower cervical segments may require CT due to image quality limitations from shoulder overlap. Although the precise measurement of angular values can be challenging, interobserver agreement among radiologists was notably high. In contrast, other radiographic criteria such as interspinous distance rely on external calibration tools that may not be consistently accurate. Computed tomography, while more precise, involves higher cost and radiation exposure. Taken together, these findings support the use of Cobb angle difference as a practical and non-invasive screening method for pseudoarthrosis diagnosis during postoperative follow-up. Further research should investigate the generalizability of these thresholds across different surgical constructs, including procedures involving anterior plating.

Conflict of Interest

The authors declare that there is no conflict of interest.

Funding

None.

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