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Clinical Study

What is the most accurate radiographic criterion to determine anterior cervical fusion?

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Abstract

BACKGROUND CONTEXT: The accuracy of radiographic criteria for determining anterior cervical fusion remains controversial, and inconsistency in the literature makes a comparison of published clinical results problematic. The descriptions of bridging bone are still lacking and subjective, and the interpretation of images can be influenced by the type of graft or cage used.

PURPOSE: To assess and validate the diagnostic accuracies of four radiographic fusion criteria using the results of surgical exploration.

STUDY DESIGN: Retrospective, radiographic, and comparative study.

PATIENT SAMPLE: This study included patients who required anterior or posterior exploration of a previous anterior cervical arthrodesis level(s) ranging from C3−C4 to C7−T1 for suspected pseudarthrosis or adjacent-segment pathologies. They underwent radiologic examinations to determine the four fusion criteria. We included patients whose images were taken at least 1 year after the index surgery, and 82 patients with 151 cervical segments were enrolled.

OUTCOME MEASURES: The inter- and intra-rater reliabilities and validity that correlated with the results of surgical exploration for the four fusion criteria were assessed using data (fusion or not) that were collected by two raters.

METHODS: The four published radiographic fusion criteria were interspinous motion (ISM) $<$ 1 mm and superjacent ISM $\geq$ 4 mm, seen on dynamic radiographs; conventional bridging bone, as seen on computed tomography (CT) scans; and extra-graft bridging bone (ExGBB) and intragraft bridging bone (InGBB), observed on multi-axial reconstructed CT scans. The criteria were evaluated by two raters (spine surgeons with 5 and 7 years of experience). The raters evaluated each criterion twice at two different time points, 3 to 4 weeks apart. First, ISM and conventional bridging bone on CT scans were evaluated, followed by ExGBB and InGBB, with a time interval of 4 months. This Research was supported by the Chung-Ang University Research Grants (less than 5,000 US dollars) in 2016.

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RESULTS: The inter- and intra-rater reliability values of the ExGBB (0.887−0.933) criteria were the highest, followed by those for the ISM (0.860−0.906), bridging bone (0.755−0.907), and InGBB (0.656−0.695) criteria. The validity values that correlated with the exploration results were the highest for the ExGBB criteria (k=0.889), followed by the ISM (k=0.776), bridging bone (k=0.757), and InGBB (k=0.656) criteria and ExGBB showed the highest sensitivity (91.7%) and specificity (98.4%). Regarding the graft materials that were used, all criteria had the highest values in the auto-cortical group and lowest values in the cage group. Of note, sensitivity and specificity of ExGBB were 100% in autocortical group. In the cage group, the validity values for the ExGBB (k=0.663) and ISM (k=0.666) criteria were higher than those for the bridging bone (k=0.504) and InGBB (k=0.308) criteria

CONCLUSION: The presence of ExGBB (anterior, posterior, or lateral to the graft or cage) correlated the best with surgical exploration. The ISM criteria demonstrated a similar accuracy to that of conventional bridging bone criteria on CT scans. In arthrodesed segments with auto-cortical bone, criteria showed the highest validity values. In cage group, ISM and ExGBB had acceptable accuracy, but the conventional bridging bone and InGBB were worse than guessing. We recommend that ISM and ExGBB criteria should be used to increase accuracy in patients who undergo arthrodesis with cages.

Keywords: Anterior cervical fusion; Fusion criteria; Interspinous motion; Bridging bone; Reliability; Pseudarthrosis

Introduction

Numerous methods for assessing fusion status following anterior cervical arthrodesis have been examined in the literature. Surgical exploration has been considered the gold standard for assessing fusion status; however, it has limited clinical utility. Although several radiographic fusion criteria have been suggested [1−7], the most accurate among these compared with intraoperative exploration remains to be determined.

Among the various radiographic modalities [1,3,5−10], computed tomography (CT) scan has been considered the gold standard non-invasive procedure. However, descriptions regarding bridging bone are subjective and still lacking and the type of graft or cage can influence the interpretation of images.

Although more stringent and uniform criteria are needed [10] especially, when clinical trials assess new interbody fusion device or material, non-validated or vague fusion criteria have been used and the determination of fusion might be influenced by an individual surgeon's perspective [11−14]. Such an inconsistency in the literature regarding determination the fusion status makes a comparison of published clinical results problematic.

The purpose of this study was to compare the accuracy of four radiographic fusion criteria in determining anterior cervical fusion status: (1) interspinous motion (ISM) <1 mm as the cutoff value with superjacent ISM ≥4 mm as observed on 150% magnified dynamic flexion and extension cervical radiographs [2], (2) conventional bridging bone on CT scan and (3) extra-graft bridging bone (ExGBB), and (4) intra-graft bridging bone (InGBB) observed on multi-directional reconstructed CT scans [4].

Materials and methods

Patients and data

This retrospective radiographic study was approved by the Institutional Review Board. The subjects were consecutive patients who required anterior or posterior exploration of a previous anterior cervical arthrodesis level(s) ranging from C3−C4 to C7−T1 for suspected pseudarthrosis or adjacent segment pathologies, from April 2004 to April 2012. The time between the index operation and surgical exploration was at least one year. We included patients with radiographic images that were available on a computer working station using a picture archiving and communication system (PACS, Siemens Magic Software, Germany, precision of 0.1 mm) to evaluate the following four anterior cervical fusion criteria: ISM <1 mm and superjacent ISM ≥ 4 mm, as seen on dynamic radiographs [2]; conventional bridging bone, as seen on CT scans; and ExGBB [4] and InGBB [4], observed on multi-axial reconstructed CT scans. The CT scans and plain radiographs were taken within 1 month before the surgical procedure. We excluded patients with any concomitant posterior operations, a fusion status that was not determined in their medical records, corpectomies and pathological, infectious, or traumatic diagnoses. We only included patients in whom we determined that solid fusion or pseudarthrosis had occurred. Any patient for whom there was any doubt was not included.

Two raters (spine surgeons with 5 and 7 years of experience) collected data and rated the patient's fusion status using all four radiographic fusion criteria. The raters evaluated each criterion twice at two different time points that were 3 to 4 weeks apart. First, ISM and conventional bridging bone as seen on CT scans were evaluated followed by

ExGBB and InGBB with a time interval of four months. Images of each cervical segment that was operated upon were interpreted to determine the fusion or nonfusion according to each criterion.

Surgical procedures

A senior surgeon performed all surgical explorations at a single academic tertiary care center. The technique for determining the fusion status during anterior or posterior surgical exploration was described in previous study [2]. Briefly, the fusion status was determined using microscopic visualization. In patients with plates, the plate was removed. If the screws were loose, we considered that solid fusion might not have occurred, although we never considered this to be the sole deciding criterion. It was not uncommon for patients with anterior fusion to have a veneer of what appeared to be bridging bone. Therefore, a minimum of 1 to 2 mm of anterior bone was removed. If there was still a question, a Caspar distractor was used to try to distract the arthrodesed level. A pseudarthrotic cleft would then become obvious. There was motion in all cases that were rated as non-union. Occasionally, a more extensive exploration procedure was required, wherein we burred down into the fusion mass to determine that there was good bridging bone across the entire disc space. For patients who underwent posterior exploration, fusion was determined if one or both facets or the interlaminar or interspinous process areas were fused. Gross interspinous process motion without facet fusion was rated as pseudarthrosis. Equivocal cases were excluded.

Plain radiographic criteria

The plain radiographic ISM criteria for fusion was defined as ISM <1 mm at the arthrodesis level and ISM ≥4 mm at a non-arthrodesed superjacent level, based on 150% magnified dynamic radiographs that were stored in PACS. These criteria are well-accepted in the literature and endorsed by the Cervical Spine Research Society [2]. Non-arthrodesed superjacent ISM criteria were used to determine whether the patient flexed and extended his or her neck adequately (Fig. 1).

CT radiographic criteria (Fig. 2)

There were two protocols for CT criteria. First, the conventional bridging bone criterion for fusion was defined as the presence of bridging bone and/or the lack of radiolucency at the graft-vertebral junction, in which the axis of the coronal and sagittal planes were fixed and could not be changed by interpreter. Second, to determine the presence of the ExGBB and InGBB, the axis of coronal, sagittal, and axial plane at each segment could be changed in a previously reported manner using an Extended Brilliance Workspace 4.5 workstation (V4.5.2.4031, Philips Healthcare Nederland BV, the Netherlands) [4]. ExGBB was defined as any bridging bone outside the graft or cage without a transverse lucent line crossing the peripheral margins of the operated disc space. Four peripheral margins were evaluated: the anterior and posterior margins on sagittal views and left and right margins on coronal views. Bridging bone with cortical density that was present in at least one of these four peripheral margins was categorized as fused. InGBB was defined as any cortical or trabecular bridging bone without a transverse, lucent line within the confines of the graft or cage and that was not outside the graft or cage. Bridging bone that was apparent on both coronal and sagittal views was defined as fused, based on both the ExGBB and InGBB criteria.

Statistics

Demographic data were expressed as the mean (95% confidence interval [CI]) or absolute number. Cohen's κ kappa value (95% confidence interval CI) was reported, and the level of agreement for the κ kappa value was

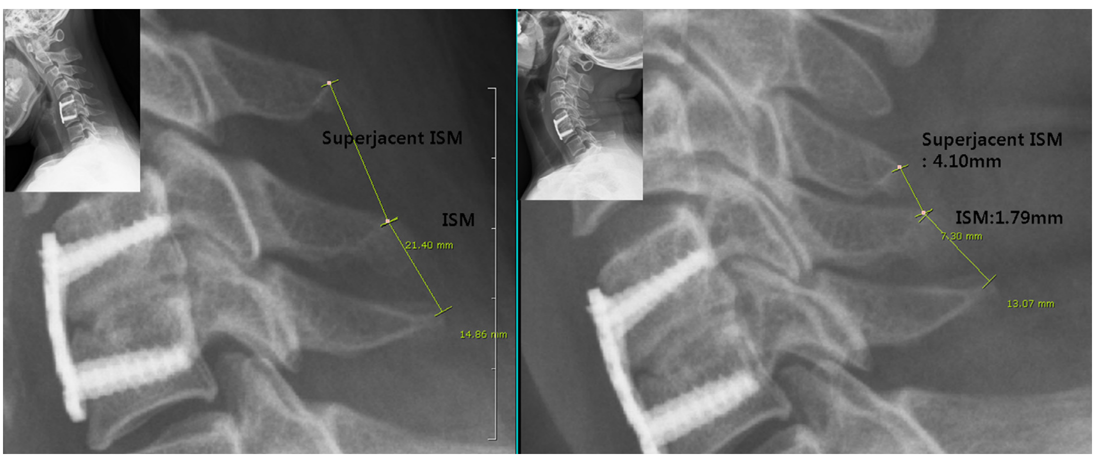

Fig. 1. Measurement of ISM at the surgical (C5−C6) and superjacent levels (C4−C5). Superjacent ISM was 4.10 mm, which means effective dynamic motion, and ISM of 1.79 mm was interpreted as non-fusion.
ISM: interspinous motion.

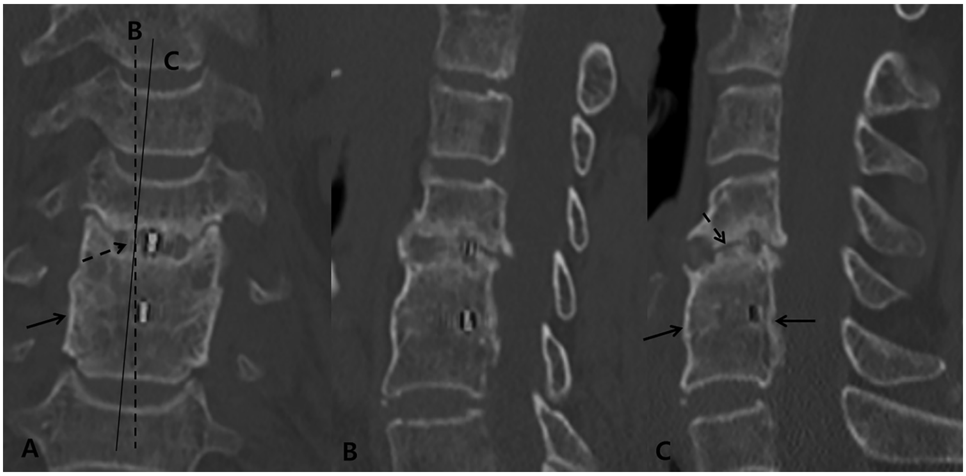

Fig. 2. Two protocols for CT criteria. In evaluating conventional bridging bone, the axis of axial, coronal, and sagittal planes were fixed and cannot be changed by interpreter on PACS (B). On the other hand, in evaluating ExGBB and InGBB, the axis of three planes can be set by interpreter using software program (C). On set coronal and sagittal planes (A and C), The C5-C6 level shows ExGBBs (arrows: anterior, posterior, and right aspects) and InGBB (dotted arrow) and ExGBB were not present at the C4-C5 level.

Table 1
Demographic data.

	Fused sgs (64 sgs/ 42 pts)	Pseudarthrotic sgs (87 sgs/ 62 pts)
Mean age at the time of revision surgery (y)	52.95 (95% CI: 50.41−55.48)	50.47 (95% CI: 47.94−53.0)
Male:female ratio (No. of pts)	16:26	29:33
Cervical level C34/C45/C56/C67/C71 (No. of sgs)	7/17/26/12/2	4/13/35/31/4
No. of anterior/posterior explorations	28 sgs in 20 pts / 36 sgs in 22 pts	22 sgs in 19 pts / 65 sgs in 43 pts
No. of anterior/posterior explorations because of adjacent sgs pathology	15 sgs in 9 pts / 4 sgs in 3 pts	

sgs: segments; pts: patients; CI: confidence interval.

determined according to Landis et al.'s method (0.01−0.20: slight agreement, 0.21−0.40: fair agreement, 0.41−0.60: moderate agreement, 0.61−0.80: substantial agreement, and 0.81−1.00: nearly perfect agreement) [15]. The validity values were also expressed as sensitivity and specificity as well as Cohen's kappa value.

Results

Patients

Eighty-two patients with 151 cervical segments were enrolled. We performed reoperations to rule out pseudarthrosis in 70 patients with 122 segments and for adjacent-segment pathology in 12 patients with 29 segments. In these patients, any previously arthrodesed levels were explored. The demographic data are presented in Table 1.

Inter- and intra-rater reliability

The inter- and intra-observer reliability values that were determined by the two raters showed that the ExGBB criteria had the highest reliability (0.887−0.933), followed by the ISM criteria (0.860−0.906). Both the ISM and ExGBB criteria showed "nearly perfect agreement" between the two raters. However, for the conventional bridging bone and InGBB criteria, except for the value determined by intra-rater A, the reliability values were in "substantial agreement" with that of the conventional bridging bone criteria (Table 2).

Validity of values that correlated with the results of surgical exploration

The validity values that correlated with surgical exploration were the highest (κ=0.889) for the ExGBB criteria, followed by those for the ISM (κ=0.776) and conventional bridging bone criteria (κ=0.757). The InGBB criteria had the lowest value (κ=0.656). The sensitivity and specificity to diagnose pseudarthrosis were 87.1% and 91.4% in ISM, 83.3% and 93.4% in in conventional bridging bone, 91.6%

Table 2
Inter- and intra-rater reliabilities of each radiographic fusion criterion.

κ-Value	ISM < 1 mm	Conventional bridging bone	ExGBB	InGBB
Intra-rater A	0.906	0.907	0.933	0.695
Intra-rater B	0.867	0.775	0.947	0.656
Inter-raters A and B	0.860	0.755	0.887	0.662

ISM: interspinous motion; ExGBB: extra-graft bridging bone; InGBB: intra-graft bridging bone.

Table 3
Validity of each criterion that correlated with the results surgical exploration.

Sensitivity/Specificity (%) (κ- Value)	ISM < 1 mm	Conventional bridging bone	ExGBB	InGBB
Rater A	89.66/91.41 (0.805)	87.36/95.31 (0.820)	95.98/98.44 (0.939)	72.99/93.75 (0.642)
Rater B	84.48/91.41 (0.747)	79.31/91.41 (0.696)	87.36/98.43 (0.840)	78.16/90.63 (0.670)
Raters A+B	***87.07/91.41 (0.776)***	***83.33/93.36 (0.757)***	***91.67/98.43 (0.889)***	***75.57/92.19 (0.656)***

ISM: interspinous motion; ExGBB: extra-graft bridging bone; InGBB: intra-graft bridging bone.

Table 4
Differences in the validity of values according to the type of graft used.

Sensitivity/Specificity (%) (κ- Value)	ISM < 1 mm	Conventional bridging bone	ExGBB	InGBB
Auto-cortical graft (n=23)	93.75/91.67 (0.836)	78.13/95.00 (0.831)	100.0 / 100.0 (1.000)	96.88/96.67 (0.929)
Allocortical graft (n=81)	83.33/92.44 (0.753)	88.02/92.44 (0.802)	93.75/97.67 (0.912)	79.17/91.28 (0.699)
Synthetic cages (n=37)	91.13/83.33 (0.666)	77.42/95.83 (0.504)	86.29/100.0 (0.663)	64.52/87.50 (0.308)

ISM: interspinous motion; ExGBB: extra-graft bridging bone; InGBB: intra-graft bridging bone.

and 98.4% in ExGBB, and 75.6% and 92.2% in InGBB criteria. ExGBB showed the highest sensitivity and specificity values (Table 3).

Differences in validity values according to the grafts that were used

The graft materials included auto-cortical grafts in 23 segments, allocortical grafts in 81 segments and cages in 37 (8 metal and 29 polyetheretherketone cages). All of the fusion criteria had the highest value and nearly perfect agreement in the auto-cortical group followed by in that of the allocortical group, and demonstrated the lowest validity values in the cage group. Among the four criteria, the ExGBB criteria showed the highest sensitivity and specificity of 100% in the auto-cortical group (κ=1.000) and sensitivity of 93.8% and specificity of 97.7% in allocortical (κ=0.912) groups. In the cage group, the conventional bridging bone and InGBB criteria showed the lowest kappa values (0.504 and 0.308) and sensitivity values, 77.4% and 64.5%, respectively. In contrast, ISM and ExGBB criteria showed higher kappa values (0.666 and 0.663) and sensitivity values, 91.1% and 86.3%, respectively (Table 4) (Fig. 3).

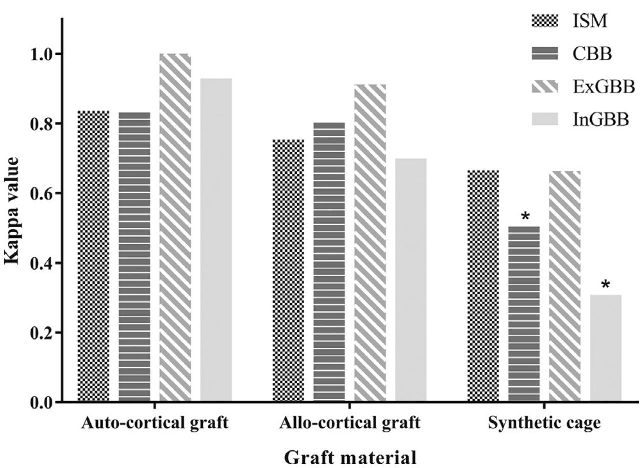

Fig. 3. A bar graph showing the different kappa values for three different graft materials. The two indicators (*) show significant low accuracy of conventional bridging bone and InGBB criteria in the cage group.

ISM: interspinous motion; CBB: conventional bridging bone; ExGBB: extra-graft bridging bone; InGBB: intra-graft bridging bone.

Discussion

We performed this study to assess and validate the diagnostic accuracy of four radiographic fusion criteria, using surgical exploration as the gold standard. The ExGBB criteria demonstrated the highest inter- and intra-observer reliability, and all agreements were "nearly perfect." In contrast, the InGBB criteria demonstrated the lowest reliability. These results are understandable because according to the ExGBB criteria, bridging bone represents new bone formation that is anterior, posterior, or lateral to the grafted bone or cage, where graft material was placed during surgery. As such, these criteria are much less prone to interpretive error than are others. In contrast, with the InGBB criteria, the interpretation of bridging bone within the cage or graft on CT scans is more often subjected to artifact and/or interpretive errors. This was especially true in our eight patients with segments with metal cages. Even when an allograft alone was used, there can appear to be bridging bone in patients with good graft apposition to the host bone in the early postoperative period (Fig. 4). We also examined the accuracy of the ISM criteria. We found that this criterion had a reliable diagnostic value, and its accuracy was comparable to that of the conventional bridging bone criteria and superior to that of the InGBB criteria.

Park et al. [16] reported that using CT scans can lead to an overestimation of the fusion rate during the early stages of anterior cervical fusion with cortical allografts, and reliably determination may require flexion-extension radiographs and high-resolution CT scans. Our results

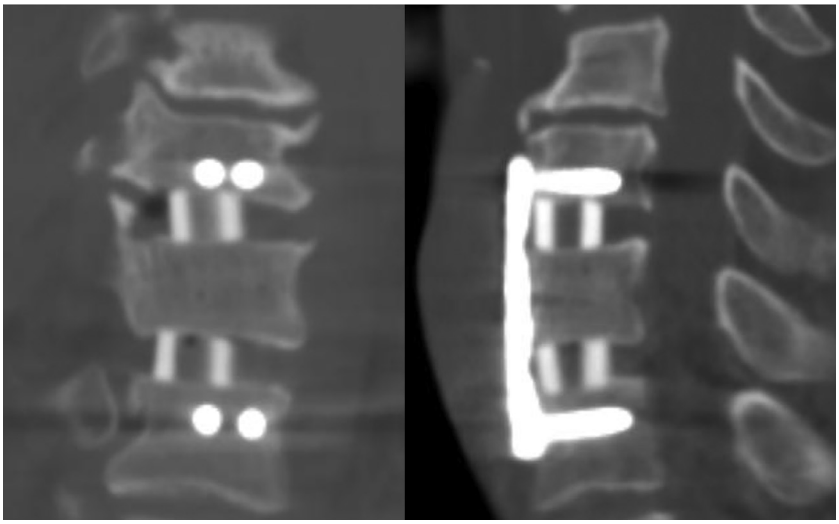

Fig. 4. A 50-year-old man underwent anterior cervical discectomy and arthrodesis at the C5−C6 and C6-C7 levels using allocortical grafts. Well-apposed grafts and vertical compression forces at the operated disc level might result in the false appearance of fusion, even on postoperative day 6.

corroborate these findings. We believe that dynamic radiographs can provide additional information regarding the fusion status, especially in patients in whom the interpretation of bridging bone is difficult, such as in those with cages. Furthermore, ISM is based upon plain radiographs, and it is associated with lower expense and radiation exposure than CT scans are. The one concern in using ISM criteria is the accuracy of measurement, especially when a 1-mm cutoff value is used. However, all inter- and intraobserver reliabilities for the ISM criteria with a 1-mm cutoff value demonstrated nearly perfect agreement in this study. We emphasize that ISM should be measured using flexion and extension radiographs that are magnified more than 150%, with a non-operated superjacent ISM cutoff value of $\geq$4 mm. Carefully selecting landmarks on both types of radiographs simultaneously on one monitor could help to increase the accuracy of this method [2].

The fusion criteria demonstrated different accuracies depending upon whether auto-cortical grafts, allocortical grafts, or cages were used. All four fusion criteria were the most accurate for the auto-cortical group and least accurate for the cage group. This is understandable, since autografts will remodel and incorporate into the host bone, and no artifacts will obscure the physician's interpretation of CT scans. In contrast, interpreting these scans is more difficult in patients with cages, since cages do not remodel or incorporate into the host bone, and metal cages may cause artifacts. In the cage group, the InGBB and conventional bridging bone criteria showed significantly low accuracy. Therefore, we suggest that ISM criteria with a 1-mm cutoff value and ExGBB as seen on CT scans should be used to increase accuracy in patients who undergo arthrodesis with cages (Table 4, Fig. 3).

There are several potential weaknesses to this study. First, it had a retrospective design. However, in a study such as this, it is not likely that a prospective design would result in a more accurate assessment of the various fusion criteria. Second, the period from the index operation to surgical exploration was significantly longer for patients with pseudarthrosis following the use of an auto-cortical graft (62.25±52.87 months) compared to the other two groups (allocortical group: 48.62 ±48.59 months and cage group: 29.35±17.35 months). However, in patients with solidly fused segments, there was no statistical difference. A longer period between the index and revision procedures in the auto-cortical group with pseudarthrotic segments might have led to higher validity values. However, all of the patients were evaluated at more than 1 year following the index operation, which is widely accepted as a sufficient period to radiographically determine the patient's fusion status [6,17]. Third, there may have been heterogeneous bone graft material in the cage group. For 18 patients, there was no information regarding the kind of material that was used. However, the purpose of this study was to demonstrate the reliability of the above-named fusion criteria, not to evaluate the differences in the fusion rate according to the bone graft material in the cages. This is also more clinically relevant, since in many cases, a surgeon who does not perform the index operation must assess the patient's fusion status without knowledge of the graft material that was used. Finally, the interpretation of dynamic radiographs requires great care, since it is critical that a physician should identify identical spots on both flexion and extension views. We have seen radiologists who use the ISM criteria without sufficient care and misinterpret the findings. Likewise, for CT scans, a radiologist must use high-quality machines with thin cuts (1−2 mm), since older machines and thicker cuts can result in reconstructed views that falsely depict solid fusion. There are no conflicts of interest for this study.

Conclusions

The presence of ExGBB (anterior, posterior or lateral to the graft or cage on reconstructed CT scans) correlated the best with surgical exploration. ISM criteria with a 1 mm cut-off value (with $\geq$ 4mm at a superjacent non-operated level, assessed on a 150% magnified image) demonstrated similar accuracy to that of the conventional bridging bone CT criteria. We echo the recommendations of the Cervical Spine Research Society, in which the ISM criteria are recommended as the most accurate plain radiographic criteria for determining fusion status following anterior cervical spine surgery. Given its advantages over CT scan in terms of cost and radiation exposure, we agree that it is the initial diagnostic test of choice for most patients. CT scan should only be taken when clinical treatment would be substantially altered by its findings. Based on used grafts, criteria showed the highest validity values in auto-cortical group. When determining the fusion status in patients who undergo arthrodesis with cages, the bridging bone criterion was no better than a flip of a coin and InGBB was worse than guessing without radiographic images, so we recommend that neither of these widely utilized criteria be used and ISM and/or ExGBB criteria are necessary to increase the diagnostic accuracy when the arthrodesis involves the use of a cage.

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Supplementary material

Supplementary material related to this article can be found at http://dx.doi.org/10.1016/j.spinee.2018.07.003.

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