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A fusion classification system for the advent of bioactive interbody implants

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Abstract

Background: Historically, intervertebral fusion required bone bridging for stability. Bioactive interbody devices enable bone integration at the endplate–implant interface, prompting an updated radiographic assessment and classification system that recognizes implant adhesion as contributing to fusion. **Aim:** This study aims to develop and evaluate a reliable computed tomography (CT)-based grading system for assessing spinal fusion and stability associated with interbody devices, including factors such as osseointegration, implant type, and bone connectivity. **Methods:** A novel fusion grading system was developed, incorporating both bone and fusion consolidation through and around the device and the apposition of bone to the implants. A total of 10 cases with one-year postoperative CT scans were provided for the survey. Surveys were administered twice, more than two weeks apart and in a different order. Inter- and intra-rater reliability were assessed using the intraclass correlation coefficient (ICC). **Results:** A total of 51 spine surgeons participated, of whom 37 completed both survey rounds. For all 51 participants, the ICC was 0.618 (95% confidence interval = 0.435–0.834; $p < 0.001$), and the mean intra-rater reliability was 0.778 (standard deviation = 0.211). Four raters had outlier intra-rater scores, with an average of 0.259. After removing these four raters (10.8% of the cohort) and analyzing the remaining 89.2% of raters, the ICC was 0.628 (95% confidence interval = 0.445–0.841; $p < 0.001$), and the mean intra-rater reliability was 0.831 (standard deviation = 0.125; $p \leq 0.015$). **Conclusions:** The novel CT-based classification system showed moderate-to-good inter-rater and good-to-excellent intra-rater reliability in clinical cases. Future work should use it to assess the relative contributions of on-growth, in-growth, and bone healing around bioactive interbody devices. **Relevance for patients:** This new classification system may be utilized to account for the stabilizing effects of bone in-growth at the implant interface when studying fusion with bioactive implants.

Keywords: Fusion classification; Interbody device; Apposition; On-growth; In-growth; Arthrodesis

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1. Introduction

Historically, posterolateral fusion techniques were most commonly used for reconstructive spine surgery; however, perceived limitations in achieving successful arthrodesis rates and adequate correction led to an increased use of interbody fusion techniques. Reconstruction of the spine has increasingly relied upon interbody fusion techniques in recent decades, largely due to efforts to improve arthrodesis rates, as well as out of necessity with improvements and success in minimally invasive surgery (in which case posterior exposure of the spine is intentionally minimized). As interbody fusion techniques and rates have expanded, there has also been an evolution in the materials and design of these implants. These technological changes have been directed toward accelerating bone healing, as our understanding of the interplay between materials science and bone biology continues to advance.

Due to the important correlation between clinical outcomes and radiographic fusion success[1,2], there has been an appropriate focus on qualitatively measuring fusion progress through various methods and classification schemes. In 1982, Pearcy and Burrough[3] were among the first to use a biplanar radiographic technique to measure small movements between vertebrae and to provide a quantitative measure and grading of bony union. They described three grades of fusion: (i) bony union with marked restriction of movement, (ii) anterior bony bar with paradoxical movement, and (iii) non-union with no restriction of movement. Many classification systems followed, all aiming to evaluate fusion status and assess potential instability after operations.[4-7] Classification systems have focused primarily on posterolateral arthrodesis and intervertebral connection, while interbody fusion assessment has largely been relegated to computed tomography (CT) analysis and evident bone continuity from one vertebra to the other. In a paradigm of allograft or autograft bone, or when considering devices that are solely intended to provide structural support while bone may connect around or through them, the assessment of bone fusion is seemingly straightforward.

However, with the advent of interbody fusion devices with microporous endplate architecture and the capacity for direct osseointegration with surrounding bone through appositional on-growth and/or in-growth, as well as facilitating fusion of one vertebra to the other through or around the device, it appears that current classification systems are likely insufficient. Because these new technologies are now being widely used in spinal reconstruction, there is a need to reconsider the manner in which we radiographically assess interbody fusion success. Therefore, in this study, we propose and assess the reliability of a novel comprehensive CT-based grading system that describes the different mechanisms by which interbody devices provide arthrodesis and/or stability to the spine. This new system accounts for both the osseointegration (on-growth/in-growth) observed with bioactive implants, as well as direct vertebral connectivity (bone bridging), thereby accommodating more inert interbody implants.

2. Materials and methods

We developed a novel intervertebral fusion grading system (**Figures 1–4**) that captures fusion consolidation through and around the interbody device as well as osseointegration—the apposition of bone to the implant surface through on-growth and in-growth. Given the recognized importance of osseointegration for segmental stability and the likely durability of clinical outcomes, we included this feature in the radiographic assessment classification scheme. The scheme was developed using CT coronal, sagittal, and axial reformatted images given the inherent challenge of ascertaining these features of fusion and osseointegration with standard radiographs.

Four grades in this system were devised to describe three different patterns of fusion and/or cage integration and a condition of radiographic pseudoarthrosis. Fusion was staged according to the location of bone connection between vertebral endplates through (inside) the implant or around (outside) the implant, as well as according to the apposition at the implant–endplate interface.

Radiographic fusion was defined as the presence of a clear continuous intervertebral bone-to-bone or implant–endplate connection with no evidence of lucency or gap. For consistency, the following terms are used throughout. Osseointegration denotes a direct structural connection between living bone and the implant surface and encompasses both on-growth (apposition of bone onto the implant surface) and in-growth (bone growth into the porous architecture of the implant). Through-growth, or bone bridging, denotes continuous bone spanning the motion segment through or around the device. Stability denotes biomechanical resistance to motion at the treated segment, which appositional contact may confer earlier than, and partly independently of, complete bony bridging; it is distinguished here from fusion, which refers to the final bony end-state of arthrodesis. The apposition of bone to the implant was considered to have occurred when areas of bone continuity with the implant, identified as radiographic "spot welds" on the sagittal and coronal reformatted CT images, were observed. Volumetric analysis of these areas of apposition was not performed due to the lack of an evidence base for reliably using volumetric thresholds to convey mechanical or clinical meaning. For simplicity in

visually describing the classification system, only coronal cuts were used in the diagrammatic illustrations; however, application of the grading system requires the use of coronal and sagittal reformatted sequences.

Four fusion grades were defined as follows:

(i) Grade 1: Clear intervertebral bone continuity through and/or around the implant, as well as cranial and caudal implant–endplate interface continuity with no evident lucency or gaps interfering with continuity in any of those locations (Figure 1).

(ii) Grade 2: Clear intervertebral bone continuity through (Figure 2A and 2B) and/or around the implant (Figure 2C and 2D), without any appositional connection to the implant at one or both cranial/caudal implant–endplate interfaces.

(iii) Grade 3: Cranial and caudal endplate bone apposition to the implant (continuity involving a portion of the implant on both surfaces), with no clear intervertebral bone continuity through or around the implant (Figure 3A and 3B).

(iv) Grade 4 pseudoarthrosis: Absence of clear intervertebral continuous bone continuity between the cranial and caudal vertebral endplates, and no appositional connection at both cranial and caudal implant–endplate interfaces (Figure 4A and 4B).

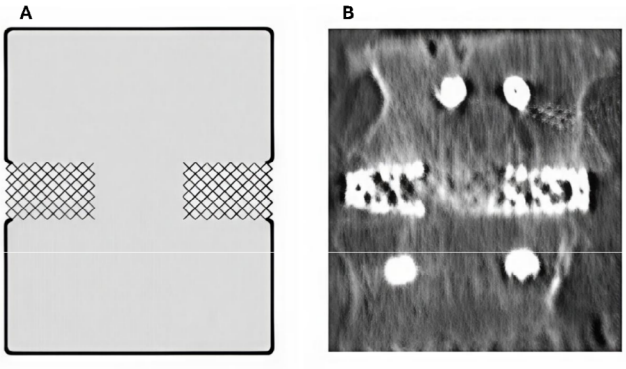

Figure 1. Graphic representation and computed tomography appearance of Grade 1 bone integration, showing bone through-growth between the vertebral endplates and bone on-growth at both implant–endplate interfaces: (A) graphic representation of Grade 1 and (B) coronal computed tomography image showing Grade 1 appearance.

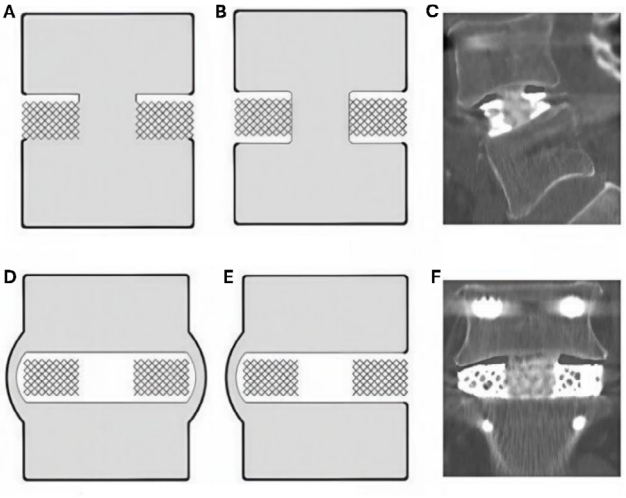

Figure 2. Graphic representation and computed tomography appearance of Grade 2 bone integration, showing bone through-growth between the vertebral endplates but no clear bone on-growth at either implant–endplate interface. (A) Graphic representation of through-growth without cranial on-growth. (B) Graphic representation of through-growth without cranial or caudal on-growth. (C) Sagittal computed tomography image showing through-growth without cranial on-growth. (D) Graphic representation of bilateral through-growth adjacent to the intervertebral implant without cranial or caudal on-growth. (E) Graphic representation of unilateral through-growth adjacent to the intervertebral implant without cranial or caudal on-growth. (F) Coronal computed tomography image showing through-growth without cranial on-growth.

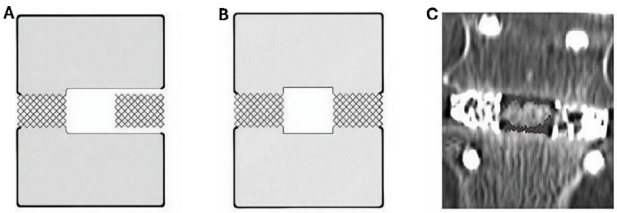

Figure 3. Graphic representation and computed tomography appearance of Grade 3 bone integration, showing no clear bone through-growth between the vertebral endplates but demonstrating bone on-growth at both implant–endplate interfaces. (A) Graphic representation of unilateral on-growth without through-growth. (B) Graphic representation of bilateral on-growth without through-growth. (C) Coronal computed tomography image showing bilateral on-growth without through-growth.

To validate this classification system, 10 clinical cases with CT scans performed greater than one year postoperatively were used in a survey and provided to a large group of orthopedic surgeons and neurosurgeons whose practice primarily focused on spine surgery for reliability assessment. Cases were identified retrospectively from patients who had undergone lateral or anterior lumbar interbody fusion with three-dimensional (3D)–printed porous titanium interbody devices and who had

CT imaging available at one year postoperatively, acquired on a GE Discovery CT750 HD scanner (GE Healthcare, United States). Case selection continued until the set included at least one representative example of each grade, as determined by the authors' consensus review. The number of cases was deliberately limited because the survey asked practicing spine surgeons from across the country to volunteer their time and complete the assessment on two separate occasions. Therefore, 10 cases were judged sufficient to span the full range of grades and to test whether raters could reliably apply the system, while remaining brief enough to preserve completion and repeat-completion rates.

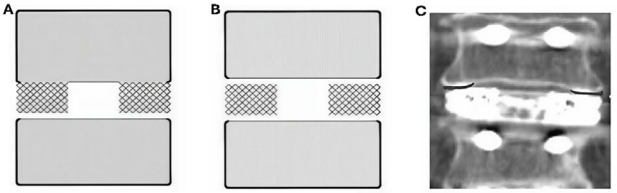

Figure 4. Graphic representation and computed tomography appearance of Grade 4 bone integration, showing no clear bone through-growth between the vertebral endplates and no definitive bone on-growth at either implant–endplate interface. (A) Graphic representation of cranial on-growth without caudal on-growth or through-growth. (B) Graphic representation of no cranial or caudal on-growth and no through-growth. (C) Coronal computed tomography image showing no cranial on-growth and no through-growth.

Surveys were administered twice to each respondent, but with cases in a different order and greater than two weeks apart. For inter-rater reliability, the intraclass correlation coefficient (ICC) estimates and their 95% confidence intervals (CIs) were calculated based on a mean-rating (k = 51), absolute-agreement, two-way mixed-effects model. For intra-rater reliability, ICC estimates were calculated based on a single-rater consistency, two-way mixed-effects model averaged across 37 raters with repeated data. The full-cohort analysis, including all participants, is reported first as the primary analysis. As a sensitivity analysis, calculations were repeated after excluding four raters identified by a single objective criterion: a non-significant intra-rater reliability ICC estimate.

Upon review, the second-round responses of these raters could not be reconciled with their first-round responses and, in some instances, were invariant across cases of clearly differing grades, indicating non-informative repeat data rather than genuine disagreement about the classification. All statistical analyses were conducted using SPSS (version 26.0.0.0, IBM Corporation, United States). ICC estimates below 0.5 were considered poor, those ranging between 0.5 and 0.75 were considered moderate, those ranging between 0.75 and 0.9 were considered good, and estimates above 0.9 were considered excellent.[8]

3. Results

A total of 51 spine surgeons participated, of whom 37 completed both survey rounds. Across the full cohort, the ICC was 0.618 (95% CI = 0.435–0.834; $p < 0.001$), and the mean intra-rater reliability was 0.778 (standard deviation = 0.211; $p \leq 0.217$). Four raters had outlier intra-rater scores, with an average of 0.259. After excluding these four raters (10.8% of the cohort) and analyzing the remaining 89.2% of raters, inter-rater reliability was 0.628 (95% CI = 0.445–0.841; $p < 0.001$), and the mean intra-rater reliability was 0.831 (standard deviation = 0.125; $p \leq 0.015$).

In general, a high degree of agreement between raters was observed in cases of complete Grade 1 fusion (on-growth and through-growth), as well as Grade 4 pseudoarthrosis (Figure 5). As expected, interobserver variability was greatest in cases of appositional on-growth (Grade 3), as this represented a novel grade distinction for participating spine surgeons (Figure 5).

4. Discussion

We have devised and presented a novel CT-based interbody fusion classification system that acknowledges advancements in implant technology, including bioactive surface characteristics, which allow for appositional on-growth and in-growth. The advent of implants that are facilitative to bone growth both through and around, as well as onto the implant, must also be considered in our assessments of these technologies when clinically applied. Successful reconstructive surgery aimed at arthrodesis depends on the stability of the target spinal segment in a durable manner but may also benefit in the short term from the stability provided by appositional connectivity of the bone to the implant.

This new classification scheme demonstrated moderate-to-good inter-rater reliability and good-to-excellent intra-rater reliability when applied to a spectrum of real clinical cases using CT. The greatest variability predictably occurred in the context of evaluating appositional on-growth/in-growth. Understandably, the proportion of surface area between the endplate and implant demonstrating continuity remains an area of uncertainty with respect to its clinical implications, and it is likely that perspectives on this issue vary amongst surgeon reviewers. However, as with other areas in orthopedic implant analysis, there does not appear to be a need for total surface area apposition to confer stability. This has been shown in

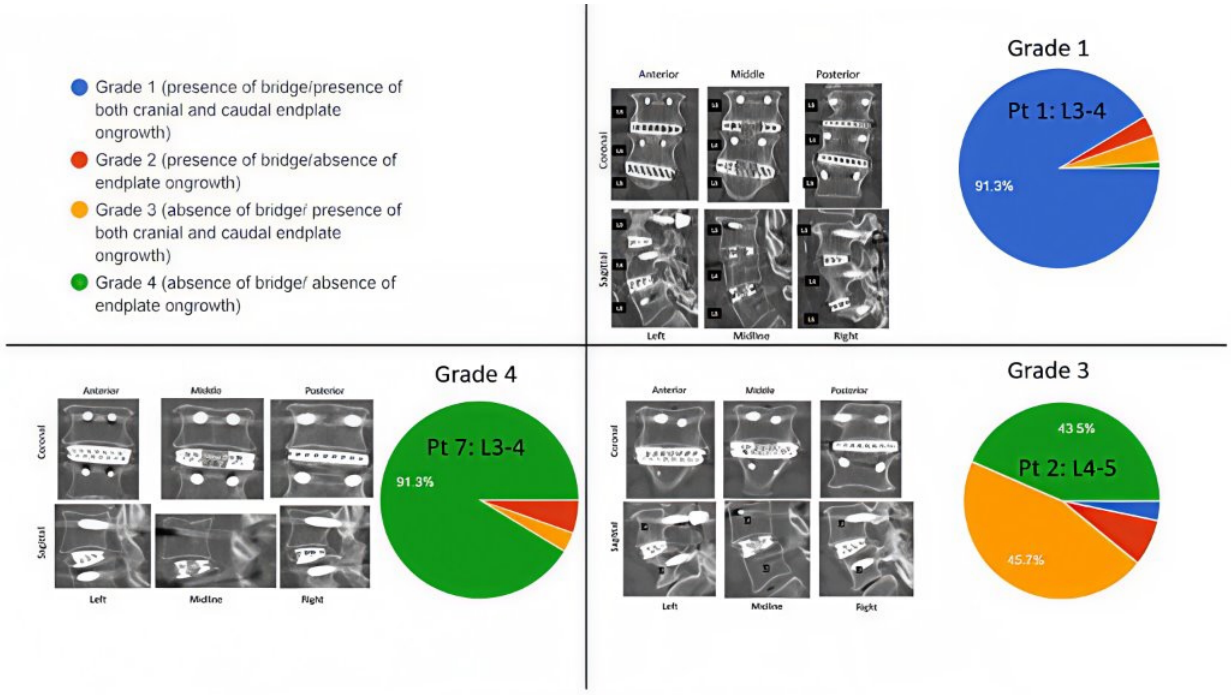

Figure 5. A graphic representation of inter-rater reliability across different fusion grades

total joint arthroplasty for hip reconstruction, where spot welds for on-growth prostheses are considered signs of stability for the femoral stem.[9] In this way, there need not be complete on-growth across the entirety of the femoral stem on radiographs to imply mechanical stability. Thus, spot-weld formation between the endplate and the implant in interbody spinal reconstruction may likewise confer the necessary stability for sustained clinical benefit.

Accurate detection of interbody arthrodesis is particularly important in patients who remain symptomatic after surgery, and the criteria for a successful arthrodesis are critical for the evaluation of new technologies aimed at achieving spinal fusion. The historic radiographic description of arthrodesis has been the presence of bone spanning a gap between two bones without evidence of radiolucency. The application of this concept to the spine has been challenging due to the limitations of conventional radiographs, the complex 3D anatomy, implants obscuring adequate visualization, and the pelvis overlying the area of interest, among other challenges. Thus, dynamic radiographs have been used extensively for fusion assessment by attempting to detect unexpected motion between the vertebrae in question after an attempted arthrodesis. Unfortunately, dynamic radiographs have not provided a reliable metric, and CT has therefore been widely considered the imaging gold standard for fusion assessment. However, there is no universal agreement on the imaging criteria for evaluating spinal fusion, and the interpretation of fusion status is often challenging. The literature is replete with methods for radiographic evaluation and grading of intervertebral fusion, but despite the availability of prior classification systems, none are ideal for the era of new interbody implant technologies.

The aims of surgical interbody fusion of two vertebrae in the lumbar spine are to provide permanent immobilization, a safe harbor for the neural elements in perpetuity, and/or a durable correction of spinal deformity. Starting in the late 1950s, interbody spinal fusion using autograft bone, allograft bone, or a synthetic interbody fusion device to facilitate fusion across the intervertebral disc space has been extensively investigated.[10] In a recent review article, eight modalities were identified for spinal fusion assessment.[11] Magnetic resonance imaging was also found to be a useful tool for the assessment of interbody fusion in select patients, especially because it markedly reduces radiation exposure[12]; however, depending on the interbody device characteristics and surrounding metal artifacts, it is not reliably consistent. However, plain radiographs, dynamic radiographs, and CT remain the most popular and effective tools for evaluation.

Plain radiographs have an important role in the routine postoperative follow-up of lumbar fusion patients. Static

radiographs have been used in the assessment of fusion status, mainly because of their low radiation exposure, low cost, and easy availability. However, there are major concerns regarding their reliability in detecting pseudarthroses, as they have demonstrated a tendency to overestimate the incidence of fusion.[13,14] Dynamic radiographs have been used to provide greater sensitivity in detecting pseudarthroses by demonstrating movement between the vertebral bodies. However, in addition to the challenges of measurement variability, there is a lack of consensus concerning the degree of detected angular change equating to a non-union, and even the absence of angular change does not necessarily imply the existence of a true arthrodesis. These dynamic radiographs often fail to detect subtle motion that is often seen in non-unions in asymptomatic patients.[15]

Computed tomography with reconstruction or reformatted images is unique in illustrating more detailed bony architecture. High-speed spiral CT allows for volume scanning, and thus overcomes the limitations of plain radiography in visualizing bone in an extrapolated 3D manner. It further allows for the demonstration of subtle differences in tissue density. This is especially true for its ability to assess bone growth onto, as well as through, the cavity of an implant. CT imaging has been shown to correlate well with histology findings, further implying that CT is likely one of the most accurate non-invasive imaging modalities for assessing fusion status.[16,17] For these reasons, the use of CT imaging for an effective and reliable fusion grading scheme for application to interbody fusion scenarios is appropriate.

There is no agreement on what precisely should be considered a "fusion" or a "non-fusion." In addition, terminology that implies ambiguity is often used to describe circumstances in many of these schemes, particularly those dependent on radiographs alone. Lenke *et al.*[4] used the terms "possibly solid" and "probably not solid" in describing posterolateral fusion patterns using plain radiography, while Brantigan and Steffee[5] used "radiographic status uncertain" to describe one of their interbody fusion grades. Even in the more recent literature, and despite the use of CT imaging in many of these studies, there are still many confusing descriptions of the fusion grades, including "minimal consolidation of bone graft indicating 1–25% healing,"[18] "doubtful fusion,"[19] "partial fusion," and "impending fusion."[6]

Currently, there is no consensus on the most relevant parameters needed for evaluation and description of interbody fusion, particularly when utilizing CT for evaluation. With advancements in both surgical and radiographic techniques, many classification systems have aimed to assess the extent, shape, maturation, and location of fusion. In a previously published CT-based classification, interbody fusion was graded volumetrically by dividing the available fusion space into eight different compartments, and the rate of fusion for each was then calculated based on the presence of bone within a portion of those compartments.[7] However, there was no accommodation for bone on-growth/in-growth in this classification scheme derived from posterior lumbar interbody constructs. In another study, the difference between the radiological density of the bone and four-square carbon cage struts on anteroposterior radiographs, as well as the status of remodeling of the grafted bone relative to the trabecular bone on CT scans, were utilized for fusion assessment.[20] The complexity of this particular scheme, which requires assessments of density and remodeling characteristics, raises concerns regarding its routine clinical application, as well as the potential for poor reliability.

Utilizing a different scheme devised by Kanemura *et al.* [20], interbody fusion was evaluated using a series of coronal and sagittal radiolucent-lesion, cage-union, and local-bone-union measurements. The clinical merit of this approach was not clarified in terms of thresholds within these various parameters that conferred stability/fusion, and more importantly, the ability to apply this type of radiographic evaluation routinely in clinical practice represents an additional concern. More importantly, these previous systems were not designed to accommodate the contribution that endplate–implant continuity through on-growth/in-growth likely confers from a mechanical perspective.

Osseointegration of load-bearing orthopedic implants is critical to long-term biomechanical functionality, as is seen in much of orthopedic care today, and it may be of similar importance in spine surgery if successfully harnessed and translated. Interbody fusion classically occurs as a bone connection between the two adjacent well-prepared vertebral endplates. When utilizing a cage or nonbiologic device, arthrodesis usually occurs through autologous or synthetic bone graft, facilitating creeping substitution and progressive bone connectivity through the cage. This will constitute a column of fused bone directly connecting the two vertebral endplates through the cavity of the cage. With the advent of porous coating and 3D printing technology, there is additional osseointegration between the cage surface and the vertebral endplate directly. The surface of these cages has a complex internal architecture and structural pores that create complex internal geometries and a rough surface architecture to increase osteoblastic activity and allow direct incorporation into bone.[21] This incorporation or osseointegration deserves a separate

radiographic evaluation in any assessment of intervertebral fusion with these novel implants, particularly due to the provision of additional and likely earlier mechanical stability.

This concept is not entirely novel in the assessment of interbody spinal fusion implants. In one study of lumbar fusion, the radiological indicators of implant–endplate "fusion" were the absence of lucency at the implant and vertebral body interface, lack of cage subsidence, and lack of endplate cystic changes on CT imaging.[22] Another proposed method was to quantify the amount of bone traversing the intervertebral disc through or adjacent to the cage; more than 50% of the operative level was considered definitely fused.[23] However, the contact considered in this scenario was not necessarily indicative of on-growth or apposition of bone to the implant. These alternative fusion assessment proposals were not explicitly designed to distinguish standard bone-to-bone connection between vertebrae from the contribution of appositional integrity between bone and implant surfaces. Additionally, the reliability of these other systems was not addressed in a formal manner.

An important consideration when grading fusions, even with CT technology, is the use of slowly resorbing or non-resorbable ceramic grafting materials, such as hydroxyapatite, which can misrepresent intervertebral bone connectivity. A variety of ceramics (e.g., hydroxyapatite, β-tricalcium phosphate, and calcium phosphate) are commonly used in spinal fusion, and their differential resorption characteristics must be considered when radiologically assessing fusion.[24] The attenuation of a well-packed synthetic graft can appear similar to bone on radiographs or CT images, and this may cause an appearance suggestive of fusion. Scrutinizing for the presence of radiolucent halo demarcation within the graft or at the graft–endplate interface is critical, as this finding is a hallmark of the resorption phenomenon that can occur and may be representative of a non-union; however, this finding may be difficult to ascertain with some ceramics.[25] Given these specific concerns over radiologic confirmation of bone connectivity in the presence of certain ceramics, there is even greater need to identify other factors representative of essential fusion, such as the implant–endplate apposition.

Although considered in some grading systems of interbody fusion assessment, subsidence does not necessarily correlate with the attainment of solid arthrodesis. The occurrence of subsidence may impact clinical results in a negative manner and theoretically could delay the achievement of mechanical stability, depending on the timing of the event. However, bone healing through, onto, and/or around an interbody implant subsequent to subsidence would not reasonably be expected to be adversely impacted by the event alone. For this reason, subsidence was not considered an essential component of this classification scheme. Importantly, the earlier appositional on-growth/in-growth with many of these implants, when compared to the endplate connectivity through or around the implant, may result in a lower incidence of subsidence. Although this may be an interesting implication of using newer interbody implant technology, particularly given the potential impact on clinical outcomes dependent on indirect decompression of neural elements, as well as alignment changes, the validity of arthrodesis assessment remains a distinctly different aim.[26] This classification has already been applied to assess fusion in clinical series of bioactive lateral and anterior lumbar interbody reconstruction.[27,28] Future assessment of interbody fusions should consider the utilization of this new system to address the important contribution of appositional on-growth/in-growth, along with traditional bone healing through and around implants.

One of the limitations of this new classification scheme and validation of its reliability is the need for CT to evaluate fusion. Standard radiographs can be more challenging to utilize given their two-dimensional nature of such imaging and the additional constraint that metal implants often obscure clear visualization of bone growing through the implant. The inability to clearly scrutinize the endplate–implant interface with implant obliquity relative to the imaging plane also leads to a challenge in consistently using plain radiographs for definitive identification of appositional adherence. We acknowledge the need to potentially find ways of using plain radiographs to assist in routine clinical assessment of fusion status; however, as with prior fusion assessment schemes, CT has been necessary for high-level clarity in fusion determination. While clinical studies may also utilize dynamic radiographs to further evaluate fusion integrity in future validation of these newer implants, additional factors that support construct stability may also be considered, such as fixation loosening/failure. In this way, future evolution of this classification may consider the incorporation of "modifiers," with loose fixation being a factor that identifies concern that intervertebral stability may be insufficient when volumetric connectivity of endplate-to-endplate or endplate-to-implant bone continuity is limited.

5. Conclusion

Advances in materials science have led to widespread adoption of bioactive interbody implants that promote integration of bone at the endplate–implant surface. Traditional fusion grading schemes do not account for the

stabilizing effects of this appositional in-growth. To address this, we developed a new CT-based interbody fusion classification system that accounts for both traditional bone through-growth and on-growth at the endplate–implant interface. A survey of 51 spine surgeons who evaluated the new grading system found moderate-to-good inter-rater reliability and good-to-excellent intra-rater reliability when applied to a spectrum of real cases. This new classification system may be utilized to account for the stabilizing effects of bone in-growth at the endplate–implant interface when studying fusion with bioactive implants.

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Conflict of interest

The authors declare they have no competing interests.

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Ethics approval and consent to participate

This study was approved by Scripps Institutional Review Board (Approval No.: IRB 13-6297).

Consent for publication

Consent for publication was not required.

Availability of data

Data is available from the corresponding author upon reasonable request.

Further disclosure

This work has been presented at the Spine Summit 2021–37th Annual Meeting of the Section on Disorders of the Spine and Peripheral Nerves on July 28–31, 2021, in San Diego, California, United States of America.

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