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Reliability assessment of new radiographic scales to evaluate radiolucency and bony in-between fin growth of partially cemented all-polyethylene glenoid components

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Background: Current methods available for assessment of radiolucency and in-between fin (IBF) growth of a glenoid component have not undergone interobserver reliability testing for an all-polyethylene fluted central peg (FCP) glenoid. The purpose of this study was to evaluate anteroposterior radiographs of an FCP glenoid component at ≥48 months comparing commonly used scales to a new method adapted to the FCP. Our hypothesis was that the new method would result in acceptable intra- and interobserver agreement and a more accurate description of radiographic findings.
Methods: We reviewed ≥48-month follow-up radiographs of patients treated with a primary aTSA using an FCP glenoid. Eighty-three patients were included in the review. Radiographs were evaluated by 5 reviewers using novel IBF radiodensity and radiolucency assessments and the Wirth and Lazarus methods. To assess intraobserver reliability, a subset of 40 images was reviewed. Kappa statistics were calculated to determine intra- and interobserver reliability; correlations were assessed using Pearson correlation.
Results: Interobserver agreement (κ score) was as follows: IBF 0.71, radiolucency 0.68, Wirth 0.48, and Lazarus 0.22. Intraobserver agreement ranges were as follows: IBF radiodensity 0.36-0.67, radiolucency 0.55-0.62, Wirth 0.11-0.73, and Lazarus 0.04-0.46. Correlation analysis revealed the following: IBF to Wirth $r = 0.93$, radiolucency to Lazarus $r = 0.92$ (P value <.001 for all).
Conclusion: This study introduces a radiographic assessment method developed specifically for an FCP glenoid component. Results show high interobserver and acceptable intraobserver reliability for the method presented in this study. The new scales provide a more accurate description of radiographic findings, helping to identify glenoid components that may be at risk for loosening.
Level of evidence: Level III; Diagnostic Study

Keywords: Shoulder arthroplasty; glenoid lucency; fluted central peg glenoid; polyethylene glenoid; radiographic review; reliability assessment; glenoid wear; glenoid failure

Total shoulder arthroplasty provides reliable pain relief and restoration of function with predictable short- and intermediate-term outcomes. However, the presence of early radiolucent lines around the glenoid component has

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been associated with eventual radiographic loosening.[3,9,14,17] Modern cementing techniques[5,10] as well as new glenoid component designs attempted to minimize the incidence of radiolucent lines and subsequent loosening. Wirth et al[15] introduced an uncemented all-polyethylene fluted central peg (FCP) glenoid. In this design, multiple circular "fins" are incorporated with the central peg of the component, allowing for press-fit central post fixation without the need for cementing. Theoretically, growth of bone between the fins of the central peg would improve component stability and diminish the incidence of glenoid loosening. Animal studies demonstrated the superiority of this FCP glenoid over keeled components with regard to pull out strength and bone growth between the fins.[15] Commercially available FCP designs, where cement is used for the 3 peripheral pegs, are a hybrid of that used in the animal studies.

The Wirth and Lazarus radiographic assessment methods have been routinely adopted for evaluation of the FCP glenoid on radiographs,[4,11,12] but neither method has undergone intra- and interobserver reliability assessment for the FCP glenoid. The Wirth scale evaluates radiodensity (RD) and was designed for an FCP glenoid component. It uses a 1-3 numeric grading system to describe osteolysis about the fins of the central peg, bone about the periphery of the fins of the central peg, and bone in contact about the periphery and in between the fins of the central peg (Table I). The Lazarus radiolucency (RL) scale was developed for the cemented peg glenoid before the newer partially cemented FCP glenoid design. It uses a 0-5 numeric scale to describe the presence of RL about 1 or more pegs (Table I) and relies on the bone-cement interface to assess the glenoid for evidence of RL.

In a study evaluating the radiographic and clinical outcomes in patients with a partially cemented glenoid, Churchill et al[1] introduced a method of assessing lucency at central peg. Their method described bone growth at the central peg as either "present" or "absent." They reported moderate interobserver agreement ($\kappa = 0.52$) between 3 musculoskeletal radiologists who assessed study radiographs. However, this method of binary evaluation lacks specificity in discerning the degree and specific location of bone growth or osteolysis about the FCP.

In order to adequately describe the appearance on anteroposterior (AP) radiographs of both in-between fin (IBF) growth and RL at the FCP glenoid as shown in Figure 1, we developed a novel assessment tool, the Total Quadrant Score (TQS), which established criteria for discriminatory evaluation of the FCP. The primary purpose of this study was to evaluate the intra- and interobserver reliability of the TQS and then compare the scores to the intra- and interobserver reliability of the Wirth and Lazarus methods when applied to the FCP glenoid. Our hypothesis was that the TQS would demonstrate acceptable intra- and interobserver agreement and provide a more accurate description of the radiographic findings for this implant. The secondary purpose of the study was to examine the level of correlation of the TQS method to the Wirth and Lazarus methods.

Materials and methods

The senior author used 1 type of FCP glenoid for all 150 anatomic TSAs that were performed from 2008 to 2012 (Affiniti; Wright Medical, Edina, MN, USA). The FCP glenoid component was implanted in partially cemented fashion, with humeral head or glenoid reamings packed in between the fins of the central peg (Fig. 2) and polymethyl methacrylate cement applied to the 3 peripheral holes. Humeral prosthetic replacement was variable, with resurfacing, short-stem, and long-stem components all used

Table I Wirth and Lazarus radiographic assessments used for FCP glenoid components

Radiographic assessment	Score	Description
Radiodensity (Wirth et al, 2012[16]): Developed for an FCP glenoid component	1	Osteolysis about the central fins
	2	Bone in contact with the periphery of the fins but no increase in radiodensity between the fins
	3	Bone in contact with the periphery of the fins of the central peg accompanied by increased radiodensity between the fins (optimal outcome)
Radiolucency (Lazarus et al, 2002[7]): Designed for cemented pegged glenoid components	0	No radiolucency
	1	Incomplete radiolucency around 1 or 2 pegs
	2	Complete radiolucency ($\leq$2 mm) around 1 peg with or without radiolucency around 1 other peg
	3	Complete radiolucency ($\leq$2 mm) around 2 or more pegs
	4	Complete radiolucency (>2 mm) around 2 or more pegs
	5	Gross loosening

FCP, fluted central peg.

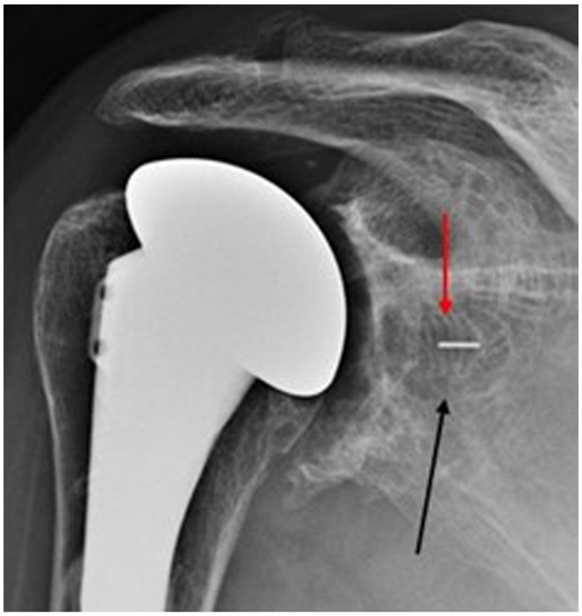


Figure 1 Anteroposterior radiograph demonstrating both fluted central peg radiolucency (↑) and bone ingrowth between the fins (←).

Figure 2 Fluted central peg implant with bone graft packed between the fins of the central peg.

with a focus on anatomic humeral head reconstruction (Aequalis Resurfacing Head, Aequalis Ascend, Aequalis Press Fit Stem; Wright Medical, Edina, MN, USA). Patients with a history of previous soft tissue shoulder surgery or proximal humerus fracture management were included but patients with prior hemi-arthroplasty or humeral head resurfacing with revision to TSA were excluded. To be included, patients had to have $\geq$48-month postoperative Grashey AP and axillary (AX) radiographs.

A TQS was developed to quantify both IBF RD and RL about the FCP. For these TQS assessments, the central peg was divided into 4 quadrants by placing a horizontal line along the central peg marker and a vertical line at the lateral edge of the marker (Fig. 3).

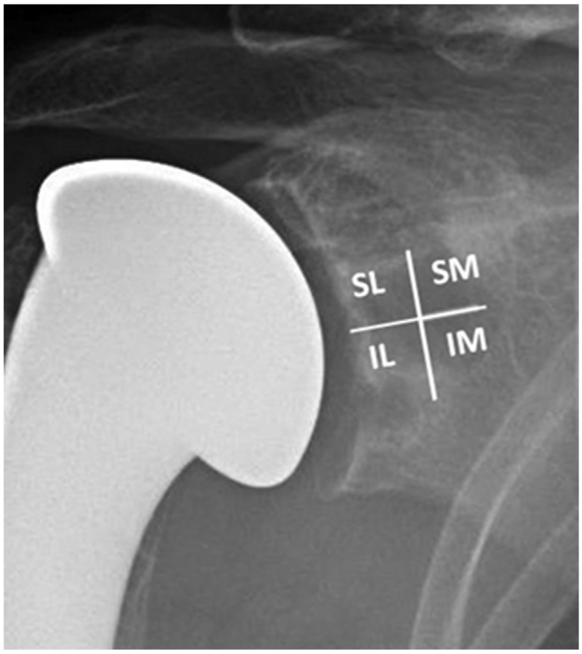


Figure 3 Fluted central peg quadrants. In-between fin radiodensity or radiolucency were assessed in each quadrant separately, and then the score in each quadrant was added to establish the Total Quadrant Score. *SL*, superolateral; *IL*, inferolateral; *SM*, superomedial; *IM*, inferomedial.

Each quadrant was scored separately for degree of RD and RL on a 0-2 scale.

To establish the TQS definitions, the examiners reviewed a subset of cohort images during 3 separate sessions coming to an agreement regarding the definitions of IBF RD and RL. Ten different images were reviewed at each of the 3 sessions. This allowed the reviewers the opportunity to refine the definitions of the assessment while minimizing the potential of becoming too familiar with the images for the final review.

For RD, the quadrant was assigned a "0" if there was no evidence of bone growth in the quadrant, a "1" if there was evidence of incomplete bone growth or sclerosis opposing the fins, and a "2" if there was definitive bone growth extending to the core of the central peg. For RL, the quadrant was assigned a "0" if there was no observed RL, a "1" if there was suspected but incomplete RL, and a "2" if there was expansile RL noted in the quadrant. The individual reviewer's quadrant scores were combined to form the TQS for IBF RD and RL for each image (Fig. 4). If a reviewer was unable to assess any quadrant, his or her score for the image was not included in analysis.

The reviewer's TQS scores were then categorized for degree of IBF RD and degree of RL. A TQS of 0-2.99 was designated as category 0, which represented "no/minimal presence" of IBF RD or RL; a TQS of 3-5.99 was designated as category 1, representing "partial" presence or IBF RD or RL; and a TQS of 6-8 was designated as category 2, which represented "near complete/complete IBF growth" if IBF RD was being assessed or "expansile RL" if RL was being assessed. The individual reviewer's category scores were used for reliability analysis. To evaluate intraobserver reliability, a random subset of 40 images

IBF Central Peg	Individual Quadrant Scores		Description
	0		No evidence of bone growth
	1		Incomplete bone growth or sclerotic appostion
	2		Definitive sclerotic line(s) along fin(s) to the core
	Total Quadrant Score	**Score Category**	**Description**
	0-2.99	→ 0	No/minimal ingrowth
	3-5.99	→ 1	Partial ingrowth
	6-8	→ 2	Near complete/complete (optimal outcome)
RL Central Peg	**Individual Quadrant Scores**		**Description**
	0		No radiolucency
	1		Incomplete/ not definitive radiolucency
	2		Expansile radiolucency
	Total Quadrant Score	**Score Category**	
	0-2	→ 0	No/minimal radiolucency
	3-5	→ 1	Partial radiolucency
	6-8	→ 2	Expansile radiolucency (at risk for loosening)

Figure 4 Total Quadrant Score system for evaluating fluted central peg in-between fin radiodensity or radiolucency and categorizing the Total Quadrant Score. *IBF*, in-between fin; *RL*, radiolucency.

Table II Interobserver reliability scores (N = 83)

Scale	Kappa
IBF scale	0.71
Radiolucency scale	0.68
Wirth radiodensity score	0.48
Lazarus radiolucency score	0.22

IBF, in between fin.
$P < .001$ for all measures.

were reassessed by all raters 7 months after completing the full cohort review.

Images were also assessed applying the Wirth and Lazarus methods to the FCP. Each reviewer's scores were used for the intra- and interobserver analysis of these scoring methods.

In order to perform a correlation analysis of the TQS method to the Wirth and Lazarus methods, an average TQS for both IBF RD and RL was calculated for each image and the average scores were categorized as previously described. The categorized average TQS IBF RD score was correlated to the overall average Wirth score, and the categorized average TQS RL score was correlated to the overall average Lazarus score.

Radiographic assessment

Four orthopedic surgeons with shoulder subspecialization, including the operating surgeon, and 1 physician's assistant with shoulder subspecialization, analyzed true AP and AX radiographs obtained at ≥48 months postoperation using the methods described. A consistent image viewing system was used by all reviewers (Quentry; Brainlabs, Munich, Germany). To minimize bias of including the operating surgeon, all examiners were blinded to patient identity and clinical outcome. AX images were assessed comprehensively by all reviewers, and it was determined that visualization of the FCP glenoid bone interface was unpredictable. Therefore, only the AP images were used for the RD and RL assessments. Available first postoperative AP and AX images were evaluated by all reviewers to determine adequate seating using the method described by Lazarus.[4]

Statistical analysis

Weighted Cohen kappa coefficient was used to evaluate the intra- and interobserver reliability of the TQS, Wirth, and Lazarus scores of the final images as well as the glenoid seating assessment.[8] Definitions as described by Landis and Koch were applied to quantify the strength of agreement: 0.00-0.20 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 almost perfect agreement.[6] No a priori sample size calculation was undertaken for the interobserver reliability analysis as all patients who met the entrance criteria were enrolled. The sample size of 40 images for the intraobserver analysis achieved 86% power to detect a kappa value of 0.75 ($\alpha = 0.05$) where there were 3 rating categories weighted at 0.23, 0.33, and 0.44. Correlation between the novel scores and the Lazarus and Wirth methods was determined using the Pearson test. An α level of 0.05 was used to determine statistical significance, and all tests were 2-sided. R Studio for statistical computing (version 3.5; R Foundation for Statistical Computing, Vienna, Austria) was used for all data analysis and statistical testing except

Table III Intraobserver reliability scores (n = 40)

	Reviewer									
	1		2		3		4		5	
	Kappa	*P* value	Kappa	*P* value	Kappa	*P* value	Kappa	*P* value	Kappa	*P* value
IBF	0.67	<.001	0.36	.003	0.61	<.001	0.63	<.001	0.60	<.001
RL	0.58	<.001	0.59	<.001	0.55	<.001	0.62	<.001	0.55	<.001
Wirth radiodensity	0.73	<.001	0.37	.001	0.11	.290	0.52	<.001	0.57	<.001
Lazarus radiolucency	0.46	<.001	0.31	<.001	0.17	.009	0.32	<.001	0.04	.600

IBF, in between fin; *RL*, radiolucency.

Table IV Correlation of Total Quadrant Score method to the Wirth and Lazarus methods

Comparison	Correlation	*P* value
IBF to RL scale	−0.84	<.001
IBF to Wirth RD score	0.93	<.001
RL scale to Lazarus RL score	0.92	<.001
Wirth RD score to Lazarus RL score	−0.83	<.001

IBF, in between fin; *RL*, radiolucency; *RD*, radiodensity.

intraobserver power analysis, in which PASS 2020, version 20.0.3 (NCSS LLC, Kaysville, UT, USA), was used.

Results

Demographics

Of the potential 150 patients, 83 (55%) met inclusion criteria. Twenty-two were deceased, 22 were lost to follow-up (contact information no longer valid), 14 had moved out of state, and 5 were revised prior to the 48-month follow-up. Reason for revision included periprosthetic fracture sustained after a fall (n = 1), infection (n = 2), humeral loosening (n = 1), and glenoid loosening at 26 months postoperation (n = 1). In this cohort (N = 83), there were 36 men and 47 women, average age at time of arthroplasty was 67.8 years (range, 43-85), and average follow-up time was 90 months (range, 48-127). Twenty patients had undergone previous shoulder surgery to include subacromial decompression or other débridement (n = 11), rotator cuff repair (n = 3), instability procedure (n = 5), or humeral open reduction internal fixation for proximal humeral nonunion (n = 1). Glenoid seating for all subjects with first postoperative images (n = 76) was assessed as "better seating" (Lazarus grade A or B[7]) by all evaluators.

Radiographic assessment agreement

There was substantial interobserver agreement for both the categorical TQS IBF RD and RL scores, $\kappa = 0.71$ and $\kappa = 0.68$, respectively, as well as with the assessment of glenoid seating ($\kappa = 0.84$). There was moderate interobserver agreement with the Wirth RD score ($\kappa = 0.48$) and fair agreement with the Lazarus RL score ($\kappa = 0.22$) (Table II). Intraobserver agreement of the TQS was acceptable (IBF RD kappa range 0.36-0.67; RL kappa range 0.55-0.62) and for most reviewers exceeded that of the Wirth and Lazarus scores (Wirth 0.11-0.73; Lazarus 0.04-0.45) (Table III). Strong correlation was noted between the IBF RD TQS and the Wirth RD scale ($r = 0.93$) and between the RL TQS and the Lazarus score ($r = 0.92$) (Table IV).

Radiographic results of the ≥48-month radiographs (mean 90.4 ± 18.8 months, median 87 months, range 48-127 months) for the TQS IBF RD score were as follows: 42 radiographs (51%) were assessed as having minimal IBF growth about the FCP, 25 (30%) with moderate IBF growth, and 16 (19%) with complete/near complete ingrowth (optimal outcome). Results of the TQS RL evaluation were as follows: 47 (57%) with minimal FCP lucency, 13 (16%) with moderate FCP lucency, and 23 (27%) with expansile FCP lucency.

Discussion

The primary purpose of this study was to evaluate the intra- and interobserver reliability of the TQS for evaluation of the all-polyethylene FCP and to compare the interobserver reliability scores to the results of the Wirth and Lazarus method when applied to the FCP. A secondary purpose of the study was to establish the level of correlation of the TQS scores to the Wirth and Lazarus methods. The results of our study demonstrated the novel TQS for assessing the FCP glenoid had high interobserver reliability, with kappa coefficients of 0.71 for RD and 0.68 for RL. Intraobserver reliability was acceptable for both RD and RL. The

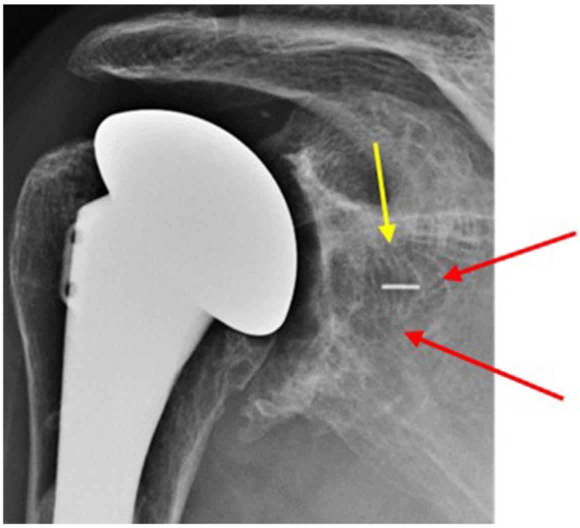


Figure 5 Assessment of standard image using the Lazarus method. *Red arrow* illustrates the areas of radiolucency, with the *yellow arrow* pointing out area without radiolucency. Score of 1 due to incomplete radiolucency about the fluted central peg but does not account for ingrowth between the fins.

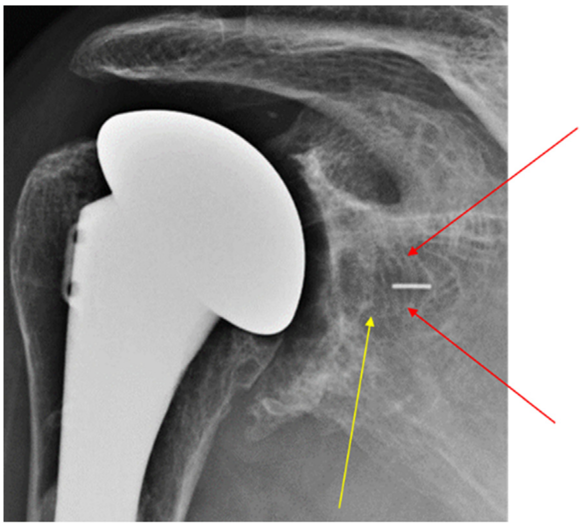


Figure 6 Assessment of standard image using the Wirth method. Probably score of 3 with bone in contact with the periphery of the fins of the central peg and radiodensity between the fins but it does not account for radiolucency around the majority of the fluted central peg.

interobserver scores were higher than those for the Wirth ($\kappa = 0.48$) and Lazarus ($\kappa = 0.22$). Additionally, we found a strong correlation to the Wirth ($r = 0.93$) and Lazarus ($r = 0.92$) methods. The benefit of the TQS score over the Wirth and Lazarus methods for the FCP glenoid is that it better describes the phenomena of both RL and IBF growth that often occurs with imaging of this implant. This potentially provides the reviewer an understanding of the progression of radiographic changes over time and the potential risk for loss of fixation of the glenoid component.

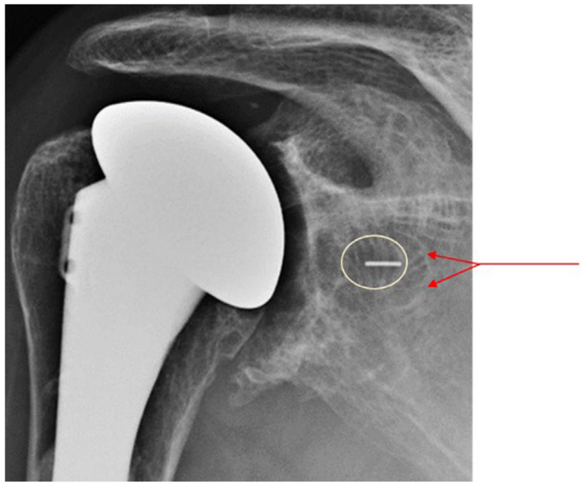
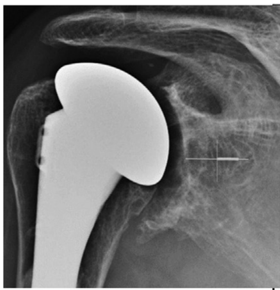


Figure 7 Assessment of standard image using the Churchill method. Circle demonstrates that the growth between the fins is "present." Radiolucency might be scored as "partial," with a numeric score of 6 along the medial and inferior aspects of the fluted central peg (FCP) and 0 along the superior FCP.

The most common glenoid radiographic assessment methods include the Lazarus score, Wirth score, and Churchill method.[1,7,16] The Lazarus method is a modification of the Franklin method that was developed to evaluate all cemented keeled glenoids.[2,7] This modified method was introduced to grade RL around all cemented pegged components. The original study was conducted using a cemented all-polyethylene glenoid component, and the bone-cement interface contrast is crucial in assessing the amount of RL around the pegs. The scoring method includes 6 grades of RL about the pegs, from 0 indicating no lucency to 5 indicating gross loosening. Grades 2-4 include a measurement of lucency (<2, >2, or 2 mm) around a specified number of pegs. The authors reported interobserver reliability of 0.55 and an intraobserver reliability of 0.57; however, these results are unclear as they used Pearson correlation (a measure of association) and Cronbach alpha (a measure of internal consistency of a measure)[13] rather than a measure of interobserver agreement. We found that the Lazarus method was potentially useful in regard to the radiographic evaluation of the peripheral cemented pegs of the glenoid used in this study but was less reliable in assessing the noncemented central peg. Despite high correlation of the TQS RL method to the Lazarus method ($r = 0.92$), we only achieved fair interobserver agreement ($\kappa = 0.22$) when the Lazarus method was used. Because there is no bone-cement interface at the FCP, we felt that accurately measuring the amount of RL about the FCP is made more difficult when using the Lazarus method.

The Wirth classification for FCP evaluation has the benefit of being relatively simple but it is difficult to reliably assign a score as in many cases the FCP has varying degrees of lysis and ingrowth, depending on the part of the peg that is assessed. The 1-3 scale attempts to quantify the



Quadrant	IBF RD score	RL score
Superolateral	1	0
Superomedial	2	2
Inferolateral	1	2
Inferomedial	2	2
TQS	6	6
Category	2: Near complete ingrowth	2: Expansile lucency

Figure 8 Assessment of standard image using TQS IBF RD and RL methods. *TQS*, Total Quadrant Score; *IBF RD*, in-between fin radiodensity; *RL*, radiolucency.

amount of bone in contact with the periphery of the FCP as well as the within the fins.[16] We observed that an evaluator must choose between the predominate pattern in each case. In addition, it is challenging in many cases to determine whether there is true bony apposition to the periphery of the pegs (positive outcome) as opposed to an early expansile cyst with a sclerotic wall. In a study assessing short-term radiographic findings in a cohort of 44 surgeries, Wirth et al reported a Cronbach α internal consistency score of 0.88 for RD and 0.91 for RL but did not fully assess inter- and intraobserver reliability (Wirth). In our study, which assessed interobserver reliability, the levels of agreement were suboptimal for RD ($\kappa = 0.48$). We believe this is related to differing opinions as to the predominate patterns of lucency and/or IBF growth. As with the Lazarus score, the strong correlation ($r = 0.93$) between our TQS IBF score and the Wirth score was anticipated in that both assess the amount of IBF growth observed.

Churchill et al described a method of evaluating the central peg lucency in which they assigned a score of 0-6 relative to the measurement of lucency across the diameter of the central peg and if the lucency was partial or complete.[1] Bone incorporation was simply described as ''present'' or ''absent'' with no option for the degree of bone formation observed about and/or in between the fins of the central peg. The method was applied to 6-week and minimum 5-year follow-up images in a cohort of 20 patients with an FCP glenoid. They reported moderate intra- and interobserver reliability ($\kappa = 0.46$, $\kappa = 0.52$ respectively) for central peg RL. No reliability assessment of bony incorporation was provided.

For purposes of this discussion, in order to further demonstrate the value of the TQS method in comparison to the Wirth, Lazarus, and Churchill methods, the 4 radiographic scoring methods were applied to a common image (Figs. 5-8). The image demonstrates a combination of bone growth between the fins of the FCP with RL around the periphery. When the image is assessed using the Lazarus method, a score of 1 (incomplete RL about 1 or 2 pegs) might be considered but the score does not account for the bone growth between the fins (Fig. 5). Applying the Wirth score to the figure (Fig. 6), the bone growth between the fins could be scored as a 3 (bone in contact with the periphery of the fins of the central peg with RD between the fins), but it does not account for the expansile RL occurring at the medial and inferior aspects of the FCP. When the Churchill method is used to assess the image (Fig. 7), bone incorporation can be described as ''present'' because of the obvious growth between the fins. However, lucency about the FCP could be scored a 6 at the medial and inferior borders of the FCP and 0 along the superior border, providing a conflicting assessment of the presumed stability of the implant. Assessment using the TQS method (Fig. 8) accounts for variability of lucency and ingrowth along the entirety of the FCP. Scoring each quadrant along a continuum of observable ingrowth results in the TQS IBF RD assessment being more discriminatory and provides the clinician a more complete understanding of the potential risk of suboptimal glenoid fixation whereas evaluating only the presence or absence of ingrowth does not quantify the amount. An additional advantage of the TQS RL score is that it does not rely on precise measurement in millimeters of RL, which is difficult to reliably achieve without fluoroscopic and magnification control. These characteristics of the TQS system likely contributed to the high agreement we observed between raters, and differences observed when compared to other measures.

There are several limitations associated with this study. First, only 55% of eligible subjects were included in the last follow-up analysis. However, this consecutive series of patients represents a much larger cohort than evaluated in other studies focused on evaluating the radiographic outcomes of this implant. Second, the images were not fluoroscopically aligned to ensure a perfectly orthogonal view of the glenoid implant, which could have affected the ability to visualize IBF growth or lucencies in all quadrants of the FCP. Finally, the images were not calibrated for measurements that could have affected the scores when using the Lazarus method of assessing RL.

The purpose of this study was limited to evaluating the reliability of this radiographic evaluation system specific to the partially cemented FCP glenoid. Subsequent studies can use this evaluation method to correlate patient outcomes of FCP glenoid components to radiographic findings of FCP RD and RL. An option for further study could involve using the Lazarus method to solely evaluate the peripheral pegs and describe in conjunction with the TQS for RD and RL, providing a hybrid method to evaluate these components in more complete detail.

Conclusions

This study introduces a radiographic assessment method with high interobserver reliability and acceptable intraobserver reliability that was developed specifically for an FCP glenoid component. The new scales provide a more accurate description of radiographic findings regarding the central peg, potentially helping to identify glenoid components that may be at risk for loss of fixation and subsequent clinical failure.

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