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## **Supplementary Files**

### **File 1: SA Radiological Monitoring v1.0 – Methodology details**

SA Radiological Monitoring v1.0

Core list of radiological parameters for shoulder arthroplasty (SA) monitoring

Overview of Delphi survey details and results

A modified Delphi technique was implemented after the selection of a consensus panel of experienced surgeons. Experienced shoulder surgeons were invited to participate after nomination by their peers within professional societies. We conducted three successive online surveys using REDCap<sup>1</sup>. Respondents to either of the first two surveys were considered panel members for this project. The main and senior authors prepared each survey; a steering committee with worldwide representation was formed before the second survey to support the formulation of a proposal for the imaging parameter definitions and specifications. Each committee member focused on various specific imaging parameters and implemented supplementary literature reviews as required to support the development and consensus process. The steering committee approved the final core set of imaging parameters for SA monitoring.

#### *First online survey*

We surveyed participants about the routinely used imaging technique(s) to monitor SA. A list of imaging parameters that may be considered as part of the monitoring protocol was presented and included radiolucency around the implant, loosening/osteolysis, implant migration with regard to the adjoining bone, signs of shoulder instability, bone formation, bone resorption, stress shielding, scapular notching, implant wear and arthritis (Supplementary File 2). For each selected parameter, participants were asked to provide their opinion on the most important features that should be considered essential for the formulation of a definition as well as the time points at which imaging parameters should be systematically monitored.

All respondents supported radiographs as the standard routine imaging technique for monitoring asymptomatic SA (Supplementary File 6). Only 10 surgeons (11%) supported the application of an additional computer tomography (CT) scan followed by magnetic resonance imaging (MRI) reported by 3 surgeons. A preliminary list of imaging parameters was agreed on and respondents provided numerous



were to be further considered except “arthritis” with only 44% supporting the inclusion of this parameter. The inclusion of the parameter “stress shielding” achieved 77% agreement, although several participants stated that this term represented a phenomenon and not a measurable entity. We therefore excluded this parameter while considering that it would manifest as a form of 'bone resorption', a term already considered within the defined parameter set. Other suggested parameters included: the integrity of the acromion; integrity of the rotator cuff; implant failure (breakage, dissociation); bone healing (e.g. in case of osteotomy or tubercle migration); and periprosthetic fractures. Rotator cuff status was not considered, since it cannot be reliably documented using standard radiographs other than via proxy parameters such as humeral head migration in asymptomatic patients. Suggested minimum time points for systematic image monitoring within and after the first 5 years were heterogeneous, and included between 1 and 7 time points from 3 months at the earliest to 5 and more years post-surgery. Radiographic monitoring at 3, 6 and 12 months was supported by 53%, 38% and 77% of respondents, respectively; 62% agreed on a 5-year radiographic check.

#### *Core set proposal and second online survey*

The initial responses were reviewed and resulted in a clear agreement among steering committee members that SA monitoring would be performed using radiographs. A second survey was prepared considering 6 groups of radiographic parameters (implant migration, radiolucency around the implant/implant loosening, signs of shoulder instability, bone resorption/bone formation/osteolysis, implant wear and scapular notching) (Supplementary File 3). Two parameters (stress shielding, arthritis) were not supported. All comments, suggested definitions and scientific references from responses to the first survey were shared anonymously with the steering committee members. The first and senior authors prepared a consolidated proposal based on all suggestions. In addition to the 6 parameters mentioned above, the parameters “osteochondral glenoid erosion” in hemiarthroplasty, “fractures around the implant”, “implant breakage/dissociation” and “bone healing” (e.g. in case of osteotomy or tubercle migration) were considered. In this survey, we also asked participants to indicate the level of severity for a radiographic observation to exhibit in order to be potentially symptomatic and therefore, should be considered an unfavorable event. Finally, we proposed a minimum set of radiographic views including a true anteroposterior (AP) view in 0° abduction and in a neutral position (i.e. neutral to the scapula plane), an axillary view in 90° abduction or Y-view (e.g. if axillary view cannot be obtained due to limited abduction capacity) as well as a standardized monitoring schedule with a set of radiographs within the first week and at 3 and 12 months after surgery.

Sixty-eight surgeons participated in the second survey. Proposed parameter definitions and their specifications were widely accepted by over 90% of the participants regarding our initial list from the first



survey (Supplementary File 7). Comments were helpful when considering amendments to our proposal; for instance, we changed the recording of implant migration to 3 categories (none / suspicion / definite), changed the grading of radiolucent lines, made “notching” a specific subset of bone resorption in the scapula, and replaced “implant wear” by “wear of the articular surfaces”.

Consensus agreement was reached for additional parameters: osteochondral glenoid erosion in hemiarthroplasty (70% agreement), fractures around the implant (humeral or scapula side, 83%), and implant breakage / dissociation (87%). However, bone healing was not supported (56% agreement).

Consensus (75% agreement) was also gained regarding our proposed minimum radiographic view set and schedule, but comments suggested that the 3-month time point be extended to 6 months to offer some flexibility without losing relevance.

### *Third online survey*

Responses from the second survey were reviewed by the main and senior authors and shared with the steering committee; amendments were made and implemented in a revised proposal that was presented to consensus panel members in a third survey (Supplementary File 4 and Supplementary File 8).

1. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009 Apr;42(2):377-81.



## File 2: SA Radiological Monitoring v1.0 - Delphi 01 survey screenshots

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### Consensus development of a core list of shoulder arthroplasty complications (survey 1)

Dear Colleague,

As an experienced surgeon in shoulder arthroplasty (SA), you have been nominated to participate in a Delphi process to define a core set of untoward events (including agreed terms and definitions) to be documented and evaluated during and after the procedure.

The survey starts with a general question seeking your approval regarding the chosen framework towards standardization of complication documentation in orthopedics. We then outline a series of events or group of events for you to suggest whether they should be selected in the core set as well as indicate any events that may be missing. Specific definitions, further specifications and postoperative observation periods are then considered.

We thank you in advance for your expertise and valuable support.

Kind regards

Laurent Audige, Holger Durchholz, Hans-Kaspar Schwyzer  
 Upper Extremity Department, Schulthess Clinic, Switzerland

Page 1 of 18

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**The primary objective of this project is to define a core set of untoward events occurring during and after shoulder arthroplasty (SA) along with their terms and definitions, which should be documented in clinical studies, registers and routine care.**

*Note: this online survey is the first as part of a modified Delphi exercise, which will possibly include up to 3 surveys in total. It is based on a similar development that was recently completed for events of arthroscopic rotator cuff repair\**

*\*Audigé L, Flury M, Müller AM, ARCR CES Consensus Panel, Durchholz H. Complications associated with arthroscopic rotator cuff tear repair: definition of a core event set by Delphi consensus process. Journal of Shoulder and Elbow Surgery 2016 [ePub ahead of print]*

Attachment: [Audige-2016-JSES-Complications associated with ARCR.pdf](#) (0.91 MB)

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**Do you agree to participate in this consensus development process to address the project objective?** ☒ Yes ☐ No

\* must provide value

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**How many years of surgical experience do you have in orthopedics?**

☐ 1-5 years  
☐ >5-10 years  
☐ >10-20 years  
☐ >20 years

reset

**On average, how many shoulder arthroplasties do you perform annually?**

☐ 1-20  
☐ >20-50  
☐ >50-100  
☐ >100

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Next Page >>

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## Consensus development of a core list of shoulder arthroplasty complications (survey 1)

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Page 2 of 18

### Conceptual development of the core set

This initial survey is based on a conceptual framework from previous experience in the field of arthroscopic rotator cuff repair as well as new considerations resulting from a literature review of shoulder arthroplasty (SA) complication and event terms. In the field of SA, many imaging parameters can be documented without symptoms, therefore we propose to address this issue by the following distinction:

1- Observations on imaging at follow-up controls including radiolucency around an implant, bone resorption, scapular notching, stress shielding, ....

2- Local (regional) untoward events affecting the treated shoulder that distinguish further *intraoperative* and *postoperative* events, and are considered in a hierarchical structure involving event groups and specifications.

*Note: nonlocal events affecting the rest of the body are addressed in a separate project because they are not specific to the field of SA. General consensus is being searched globally for all orthopedic interventions.*

Do you agree with this concept and developmental process?

☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 1)

Resize font:  


Page 3 of 18

### Imaging parameters

**Imaging parameters**  
 i.e. systematic controls conducted independently on the  
 occurrence of symptomatic event(s).

Which of the following **imaging technique(s)** should be routinely  
 used to monitor shoulder arthroplasties?

- ☐ Radiographs
- ☐ CT
- ☐ MRI
- ☐ Scintigraphy
- ☒ Other imaging technique(s)

Specify other imaging technique(s)

Which of the following **imaging parameters** should be considered as part of an observation protocol?

- ☐ Radiolucency around the implant
- ☐ Loosening / osteolysis
- ☐ Implant migration (e.g. subsidence, tilt, shift) with regard to the adjoining bone
- ☐ Signs of shoulder instability (e.g. dislocation, subluxation, head migration)
- ☐ Bony formation (e.g. spurs, osteophytes)
- ☐ Bone resorption (e.g. tubercula, tuberosities, cortices)
- ☐ Stress shielding
- ☐ Scapular notching (reverse SA)
- ☐ Implant wear
- ☐ Arthritis (bone, cartilage)
- ☒ Other imaging parameter(s)

Specify other imaging parameter(s)

Comment or suggestion

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<< Previous Page

Next Page >>

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## Consensus development of a core list of shoulder arthroplasty complications (survey 1)

Resize font:  


Page 4 of 18

### Timing of imaging parameter(s)

At which time points should imaging parameters be systematically monitored for all patients?

Within the first 5 years after SA

- ☐ Never  
☐ 3 months  
☐ 6 months  
☐ 12 months / 1 year  
☐ 2 years  
☐ 3 years  
☐ 4 years  
☐ 5 years  
☒ Other time point(s)

Specify other time point(s)

More than 5 years after SA

- ☐ Never  
☐ Every year  
☐ Every 2 years  
☐ Every 3 years  
☐ Every 5 years  
☐ Every 10 years  
☒ Other frequency

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Specify other frequency

Should imaging parameters be documented in addition to motion and strength in all patients reporting shoulder pain and/or loss of function after SA?

- ☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 1)

Resize font:  


Page 5 of 18

### Imaging parameter definitions

For each of the imaging parameters you previously selected as important, could you tell us the most important feature(s) that should be taken into account and/or which scientific reference(s) you consider essential for the formulation of a definition?

*Note: Based on our literature review and your feedback, we will prepare a set of definitions for your review in the second Delphi survey. We present below an example with radiolucency as to how a definition could be formulated. We suggest that future definitions should be sufficiently simple to apply to most (if not all) prosthesis types. Please specify if your suggestions apply to all or specific prosthesis type(s).*

#### Radiolucency around the implant (preliminary suggestion presented as an illustration)

**Definition :** Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant interface and is evaluated using plane radiographs according to their presence or absence, location and thickness. The humeral and glenoid components are divided into radiographic zones specific to each device (e.g. using a shaft prosthesis, the humerus is divided into 8 zones\*). The maximum thickness of the lines is measured to within 0.5 mm.

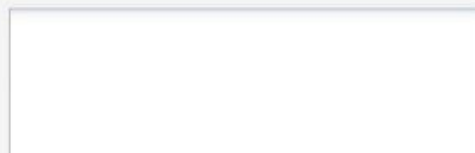
\*Sperling, J.W., Cofield, R.H., O'Driscoll, S.W., Torchia, M.E., Rowland, C.M.: Radiographic assessment of ingrowth total shoulder arthroplasty. *J Shoulder Elbow Surg*, 9(6): 507-513, 2000

**Radiolucency around the implant**



Expand

**Loosening / osteolysis**



Expand

**Implant migration (e.g. subsidence, tilt, shift) with regard to the adjoining bone**



Expand

**Signs of shoulder instability (e.g. dislocation, subluxation, head migration)**



Expand



<b>Bony formation (e.g. spurs, osteophytes)</b>	<div></div> <div>Expand</div>
<b>Bone resorption (e.g. tubercula, tuberosities, cortices)</b>	<div></div> <div>Expand</div>
<b>Stress shielding</b>	<div></div> <div>Expand</div>
<b>Scapular notching (reverse SA)</b>	<div></div> <div>Expand</div>
<b>Implant wear</b>	<div></div> <div>Expand</div>
<b>Arthritis (bone, cartilage)</b>	<div></div> <div>Expand</div>
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Consensus development of a core list of shoulder arthroplasty complications  
(survey 1)

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Page 18 of 18

Many thanks!

Do you have any general comment(s)?

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<< Previous Page

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Save & Return Later



### File 3: SA Radiological Monitoring v1.0 - Delphi 02 survey screenshots

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## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

The objective of this second survey (Part 1) is to define radiological screening parameters for SA monitoring.

We thank you in advance for your valuable expertise and continued support.

Kind regards

Laurent Audige, Holger Durchholz, Hans-Kaspar Schwyzer  
 Upper Extremity Department, Schulthess Clinic, Switzerland

Page 1 of 10

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## Radiographic parameters

i.e. systematic monitoring conducted independently on the occurrence of symptomatic event(s).

These parameters should be documented for all SA implantations irrespective of the occurrence of clinical symptoms. A priori, these observations do not represent adverse events or complications, except in the following situations:

- A parameter has reached some level of severity that is considered abnormal.
- The responsible clinician decides to carry out additional treatment, either surgical or non-surgical.
- The patient has symptoms as a result of the parameter.

Attachment: [DelphiSurvey01-01-Concept.pdf](#) (0.09 MB)

Participants of the first Delphi survey agreed on the relevance of 8 radiographic parameters that we will discuss in the following survey sections.

Attachment: [DelphiSurvey01-02-Imaging parameters.pdf](#) (0.1 MB)

**Do you agree to participate in this second Delphi survey?** ☒ Yes ☐ No

\* must provide value reset

**Did you participate in the first Delphi survey?** ☐ Yes ☒ No

\* must provide value reset

**How many years of surgical experience do you have in orthopedics?**

☐ 1-5 years  
☐ >5-10 years  
☐ >10-20 years  
☐ >20 years

reset

**On average, how many shoulder arthroplasties do you perform annually?**

☐ 1-20  
☐ >20-50  
☐ >50-100  
☐ >100

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Next Page >>

Save & Return Later



## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  


Page 2 of 10

### Radiographic parameters (1)

#### Implant migration (e.g. subsidence, tilt, shift)

Attachment:  [DelphiSurvey01-06-ImagingDef-ImplantMigration.pdf](#) (0.11 MB)

Based on a proposal by Dr. Bjorn Salomonsson (Karolinska Institutet Danderyds Sjukhus AB, Stockholm, Sweden)

**Definition of terms :** Implant migration is a noticeable change of the position of the implant, relative to the bone it is supposedly fixed to (either cemented or uncemented).

**Specifications :**

- Subsidence : migration in a specific direction. Subsidence of a humeral implant is measured relative to the highest point of the greater tubercle (but not if it is the tubercle that migrates), and a medial migration of the glenoid component relative to the base of the coracoid on AP radiographs of the shoulder. A migration should be >1 mm to be considered true in an individual case.

- Tilt : migration as a rotation of the implant. Tilt of the humeral component is measured relative to the mid-shaft line of the humerus. Tilt of the glenoid component is measured relative to the plane of the under-surface of the acromion. A tilt of >5° is considered true if the radiographs are taken in the same plane.

- Shift : migration as a combination of direction and rotation.

Brinke B.T., Beumer A., Koenraadt K.L.M., Eygendaal D., Kraan G.A., Mathijssen N.M.C. The accuracy and precision of radiostereometric analysis in upper limb arthroplasty, *Acta Orthopaedica* 2017, 88(3):320-325

Streit J.J., Shishani Y., Greene M.E., Nebergall A.K., Wanner J.P., Bragdon C.R., Malchau H., Gobeze R. Radiostereometric and radiographic analysis of glenoid component motion after total shoulder arthroplasty, *Orthopedics* 2015, 38(10):e891-e897

Valstar E.R., Gill R., Ryd L., Flivik G., Börlin N., Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants, *Acta Orthopaedica* 2005, 76(4):563-572

#### Notes

- Severity level indicating the radiographic observation as an untoward event: Implant migration is of interest in the evaluation after shoulder arthroplasty, mainly as an indication of possible loosening or malposition that is to be regarded as a complication after the joint replacement. However, implant migration without any clinical symptoms or deterioration of function is not specifically defined as a complication, but may indicate a need of future monitoring of the implant. Infection and loosening may be events associated with implant migration, but these causes should be considered higher in the hierarchy of complications compared to migration.

- We accept that in some situations, the defined reference points (greater tuberosity or acromion) may not be adequate for the measurement of the respective migration parameters.

- For additional notes about implant migration, please open the attached document below.

Attachment:  [SA\\_Monitoring\\_Migration-Notes.pdf](#) (0.08 MB)

Do you agree with this definition, specifications and terminology?

☐ Yes ☐ No

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<< Previous Page

Next Page >>

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## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  


Page 3 of 10

### Radiographic parameters (2)

#### Radiolucency around the implant / Implant loosening

Attachment:  [DelphiSurvey01-04-ImagingDef-Radiolucency\\_Loosening.pdf](#) (0.19 MB)

Based on a proposal by Dr. John Sperling (Mayo Clinic, Rochester, Minnesota, USA) and Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

##### Definition of terms :

**Radiolucency** relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant, bone-cement or cement-implant interface.

Implant **loosening** is considered when respective components are identified with Grade 4 lucency (see below) or a shift in position (see previous section) between postoperative radiographs (implants at risk of failure based on radiographic outcome).

##### Specifications :

RLL are documented according to their presence or absence, location and thickness, separately for the humeral and glenoid components. The humeral component is further divided into metaphysis and diaphysis according to the **surgical neck** of the humerus (visible on standard radiographs).

Within each of these locations (as appropriate for various prosthesis types), the severity of RLL occurrence is graded as follows:

Grade 0 : None (any RLL are < 0.5mm in width)

Grade 1 : Incomplete RLL < 1.5mm in width

Grade 2 : Incomplete RLL reaching 1.5mm in width

Grade 3 : Complete with some RLL < 1.5mm in width

Grade 4 : Complete with all RLL reaching 1.5 mm in width (loosening)

*Sperling J.W., Cofield R.H., O'Driscoll S.W., Torchia M.E., Rowland C.M. Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg 2000, 9(6): 507-513*

*Schoch B.S., Barlow J.D., Schleck C., Cofield R.H., Sperling J.W. Shoulder arthroplasty for post-traumatic osteonecrosis of the humeral head. J Shoulder Elbow Surg 2016, 25(3):406-412*

##### Notes

- Severity level indicating the radiographic observation as an untoward event: development of symptoms, implant loosening (Grade 4 lucency) and/or revision of arthroplasty.

- Loosening could be aseptic or due to infection. In the latter case, infection is the leading adverse event.

Do you agree with this definition, specifications and terminology?

☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  


Page 4 of 10

### Radiographic parameters (3)

#### Signs of shoulder instability

Attachment:  [DelphiSurvey01-07-ImagingDef-ShoulderInstability.pdf](#) (0.11 MB)

Based on a proposal by Dr. Philipp Moroder (Charité Universitätsmedizin Berlin, Germany)

**Definition of terms :** Shoulder instability refers to a loss of alignment of the articulating surface of the humeral component with the articulating surface of its joint partner.

**Specifications :**

- Static instability: non-arm position-dependent eccentric misalignment with residual contact visible on standard radiographs.
- Dislocation: non-arm position-dependent complete loss of contact visible on standard radiographs.

**Notes**

- Dynamic instability (arm position-dependent loss of contact) requires functional radiographs (horizontal flexion/extension view in 90° of abduction or otherwise, if that cannot be achieved by the patient, internal and external rotation AP view in 0° of abduction, as well as true AP view in 60° of abduction) and therefore, cannot be documented in routine monitoring of asymptomatic patients using standard radiographs. Functional imaging is recommended only in the case of clinically suspected dynamic instability (i.e. in the presence of symptoms). This event is therefore addressed in the Core Event Set.

- Severity level indicating the radiographic observation as an untoward event: A dislocation is considered an adverse event/complication regardless of symptoms or required revision surgery. Static and dynamic instability are only considered as adverse events/complications in the presence of symptoms or required revision surgery due to eccentric component wear or bone loss.

Do you agree with this definition, specifications and terminology? ☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  


Page 5 of 10

### Radiographic parameters (4)

#### Bone resorption / Bone formation / Osteolysis

Attachment:  [DelphiSurvey01-09-ImagingDef-Bone resorption\\_Formation\\_Osteolysis.pdf](#) (0.13 MB)

Based on a proposal by Dr. Simon Lambert (University College London Hospital, London, UK)

**Definition :** Bone resorption: the progressive disappearance of bone from the humerus and/or scapula following SA when compared to the preoperative condition.

Bone formation: the progressive apposition of bone on or in the humerus and/or scapula following SA when compared to the preoperative condition, more than that required for stable integration of the prosthesis.

- Homotopic bone formation (homotopic ossification) is bone formation within the confines of the bone including the periosteum: bone is formed within tissue that is destined to be or become bone under normal healing or loading conditions.

- Heterotopic bone formation (heterotopic ossification) is a subset of excess bone formation within or between tissues that is not destined to be or become bone under normal healing or loading conditions.

**Specifications :**

Bone region-based description of periprosthetic occurrence / extent of bone resorption / formation:

- Humeral side: further divided into metaphysis and diaphysis according to the surgical neck of the humerus (visible on standard radiographs).
- Glenoid side (without further division)

Heterotopic bone formation is classified according to the Brooker classification\*

\*Brooker AF, Bowerman JW, Robinson RA, Riley Jr LH. Ectopic ossification following total hip replacement: incidence and a method of classification. JBJS 1973;55:1629-1632.

#### Notes

- The terms osteopenia (diminished bone quality or density) and osteolysis (absent bone) may be considered synonyms that should be avoided, since they imply an observation at a specific point in time rather than a progressive disease. The term osteolysis is often used in association with more actively destructive bone loss such as that seen in oncological disease or fulminant infection, where the disequilibrium between bone destruction and bone formation favours the former. It is a subset of bone resorption. However, the term osteolysis is often used indiscriminately and does not always imply active destruction. In this sense, the term is unhelpful. We suggest that bone resorption is the more useful term, since it actually describes what is seen on imaging and in histology but does not imply or define a specific disease process.

- Radiographic features show absence or hypo-density of bone previously present or of normal quality (manifest as "lucent lines", loss of bone structure or density, loss of bone mass), yet detection in a series of radiographs is poorly reliable. Radiographic screening in asymptomatic patients can raise suspicions of bone resorption; CT imaging should be used to confirm bone resorption status in symptomatic patients.

- Severity level indicating the radiographic observation as an untoward event: In the presence of symptoms or required revision surgery due to associated implant loosening.

Do you agree with this definition, specifications and terminology?

☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later





## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Page 6 of 10

### Radiographic parameters (5)

#### Implant wear

Attachment:  [DelphiSurvey01-12-ImagingDef-Implant wear.pdf](#) (0.1 MB)

*Based on a proposal by Dr. Richard Page (Deakin University, Burwood, VIC, Australia)*

**Definition :** Damage, erosion or loss of surface material of an implant over time, usually due to friction. Biologically active particles generate an inflammatory response including osteolysis that may result in bone resorption and/or loss of fixation of the implant.

**Specifications :**

- a) Articular surface: reduction of joint space observed on serial plain radiographs (concentric or eccentric wear).
- b) Change in position of a prosthesis at:
  - Bone-implant interface (glenoid, humerus)
  - Cement-implant interface (glenoid, humerus)
  - Modular implant interface (eg. humeral head-neck, metaglene-glenosphere)

*Gunther S.B., Graham J., Norris T.R., Ries M.D., Pruitt L. Retrieved glenoid components: a classification system for surface damage analysis. The Journal of arthroplasty 2002, 17(1):95-100*

*Terrier A., Merlini F., Pioletti D.P., Farron A. Comparison of polyethylene wear in anatomical and reversed shoulder prostheses. Bone & Joint Journal 2009, 91:977-982*

#### Notes

- The ability to determine wear is based on visualising reduction in the joint space or bone resorption (caused by osteolysis) at one or another bony junction - determination on plain radiographs is limited unless the degree of wear is at an advanced stage. The use of CT scanning with metal suppression software is useful to differentiate osteolysis from wear, particularly with polyethylene components. The use of triple-phase bone scans and SPECT CT is helpful to differentiate loosening from wear, particularly around metal-bone interfaces (but this is not possible using imaging alone to differentiate from septic loosening). CT scans, however, cannot be considered in a monitoring context of all SA.

- Severity level indicating the radiographic observation as an untoward event: When leading to loss of prosthesis position, instability of the prosthesis (loosening?), and/or resulting in symptoms (pain) leading to reoperation or component revision.

Do you agree with this definition, specifications and terminology? ☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Page 7 of 10

### Radiographic parameters (6)

#### Scapular notching (specific to reverse SA)

Attachment:  [DelphiSurvey01-11-ImagingDef-Scapular notching.pdf](#) (0.1 MB)

**Definition of terms :** Scapular bone resorption with disruption of the normal contour (= notch) near the glenoid base plate.

**Causative factors :**

- a) contact/impingement of the cup of the humeral component and the inferior bone of the scapula.
- b) polyethylene wear particles triggering osteolysis.

**Specifications :** Classification of the extent of glenoid erosion according to the Sirveaux classification\*.

- Grade 1 = notch limited to the scapular pillar
- Grade 2 = notch reaching the inferior screw of the base plate
- Grade 3 = notch extending beyond the inferior screw
- Grade 4 = notch reaching the base plate central peg.

\* Sirveaux F., Favard L., Oudet D., Huquet D., Walch G., Mole D. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. Results of a multicentre study of 80 shoulders. *J Bone Joint Surg Br* 2004; 86(3): 388-95.

**Notes**

- Although it is considered a form of bone resorption, scapular notching is a separate entity due to its direct association with reverse SA.
- The Sirveaux classification system has some limitations due to the variety of prosthesis designs and its dependency on the placement of the inferior screw of the base plate, yet we are not aware of a better alternative for documentation. This system currently remains widely accepted and used.
- Severity level indicating the radiographic observation as an untoward event: When the progression of notching is associated with implant breakage (e.g. screw), or symptomatic implant loosening or migration, or implant revision.

**Do you agree with this definition, specifications and terminology?** ☐ Yes ☐ No

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**Comment or alternative suggestion**

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<< Previous Page


Next Page >>

Save & Return Later



Radiographic parameters (7)

Other radiographic parameters were mentioned

Attachment:  [DelphiSurvey01-14-ImagingDef-OtherParameters-v2.pdf](#) (0.16 MB)

Which of the following other radiographic parameters should be considered as part of a screening protocol?

☐ Osteochondral glenoid erosion in hemiarthroplasty

☐ Fractures around the implant (humeral, scapula side)

☐ Implant breakage / dissociation

☐ Bone healing (e.g. in case of osteotomy or tubercle migration)

Note

Rotator cuff integrity was suggested, however, it cannot be reliably documented using standard radiographs other than via proxy parameters such as humeral head migration in asymptomatic patients.

Comment or suggestion

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  


Page 9 of 10

### Radiographic views, quality criteria and schedule

The timing for monitoring radiographic parameters did not reach consensus.

Attachment:  [DelphiSurvey01-03-Imaging parameters\(2\).pdf](#) (0.1 MB)

*Based on the initial proposal by Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)*

**Standard radiographic views** (fluoroscopic positioning is recommended) :

- True anteroposterior view in 0° abduction and in neutral position (i.e. neutral to the plane of the scapula)
- Axillary view in 90° abduction or Y-view (e.g. if axillary view cannot be obtained due to limited abduction capacity).

**Monitoring time frame** : First set of radiographs within the first week after implantation, a second set at three months and a third set 12 months after implantation.

#### Notes

- The following recommendation stems from the idea that long-term monitoring is only justified if any radiographic observations would lead to an additional intervention(s) before the occurrence of symptoms. There is no evidence suggesting that long-term radiographic monitoring is cost-effective as opposed to performing clinical and radiographic check-up examinations only in patients reporting symptoms. However, a minimum radiographic monitoring regime is warranted to specifically assess short-term parameter progression and should be applicable in all settings.

- We believe the true AP view in neutral position may be replaced by two views in internal and external rotation, respectively.

- Other radiographic views such as the Neer outlet view or functional radiographs (e.g. AP view in 60° abduction, axillary view in horizontal flexion as well as extension of the arm) are considered in a diagnostic context only.

Do you agree with this proposed minimum radiographic set and timeline?

☐ Yes ☐ No

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<< Previous Page

Next Page >>

Save & Return Later



Consensus development of a core set of screening parameters for shoulder arthroplasty monitoring (Survey 2 - Part 1)

Resize font:  
+ | -

Page 10 of 10

Many thanks!

Do you have any general comment(s)?

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<< Previous Page

Submit

Save & Return Later



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## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

We thank you in advance for your further expertise and valuable support.

Kind regards

Laurent Audige, Holger Durchholz, Hans-Kaspar Schwyzer  
Upper Extremity Department, Schulthess Clinic, Switzerland

Page 1 of 21

---

The objective of this third survey is to review and approve a final consensus proposal for

- 1) a core set of radiological parameters for SA monitoring**
- 2) a core set of untoward events occurring during and after shoulder arthroplasty (SA).**

---

**Do you agree to participate in this third Delphi survey?**      ☒ Yes    ☐ No

\* must provide value

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**Did you participate in the first and/or second Delphi survey?**      ☐ Yes    ☒ No

\* must provide value

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**How many years of surgical experience do you have in orthopedics?**

☐ 1-5 years  
☐ >5-10 years  
☐ >10-20 years  
☐ >20 years

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**On average, how many shoulder arthroplasties do you perform annually?**

☐ 1-20  
☐ >20-50  
☐ >50-100  
☐ >100

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Next Page >>  
  
Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:



Page 2 of 21

### Part 1: core set of radiological parameters for SA monitoring

This part of the survey concerns the monitoring of shoulder arthroplastic in ALL patients, and not the documentation of adverse events / complications. In this revised proposal we considered all comments made in the previous survey, which can be seen in attached documents in PDF format within each survey section.

In these documents we provide some explanatory notes, references and all changes to the proposal are shown **in red**.


[<< Previous Page](#)

[Next Page >>](#)

[Save & Return Later](#)



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  


Page 3 of 21

### Radiographic parameters (1)

#### Implant migration (e.g. subsidence, tilt, shift)

*Based on a proposal by Dr. Björn Salomonsson (Karolinska Institutet Danderyds Sjukhus AB, Stockholm, Sweden)*

**99% (66/67) of participants agreed about the proposed definition, specifications and terminology**

Attachment:  [DelphiSurvey02-01-ImagingDef-ImplantMigration.pdf](#) (0.12 MB)

**Definition of terms :** Implant migration is a noticeable change of the position of the implant, relative to the bone it is supposedly fixed to (either cemented or uncemented).

**Specifications :**

- Subsidence : migration of the implant along a linear axis compared to the immediate post implantation position documented in one of 3 classes:

None = no sign of subsidence

Suspicion = subsidence is suspected but with no more than 5 mm of migration

Definite = subsidence is noted with more than 5 mm of migration.

- Tilt : migration of the implant resulting in an angulation of its main axis compared to the immediate post implantation position documented in one of 3 classes:

None = no sign of tilt

Suspicion = tilt is suspected but with no more than 10° of angulation

Definite = tilt is noted with more than 10° of angulation.

- Shift : migration as a combination of subsidence and tilt. Shift is suspected when both subsidence and tilt are suspected or one is suspected and the other is definite. Shift is definite when both subsidence and tilt are definite.

**Do you agree with this definition, specifications and terminology (including changes)?**

☐ Yes ☐ No

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[Expand](#)

[<< Previous Page](#)

[Next Page >>](#)

[Save & Return Later](#)



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)



Page 4 of 21

### Radiographic parameters (2)

#### Radiolucency around the implant / Implant loosening

Based on a proposal by Dr. John Sperling (Mayo Clinic, Rochester, Minnesota, USA) and Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

**96% (64/67) of participants agreed about the proposed definition, specifications and terminology**

Attachment:  [DelphiSurvey02-02-ImagingDef-RadiolucencyLoosening.pdf](#) (0.12 MB)

##### Definition of terms :

Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant, bone-cement or cement-implant interface.

Implant loosening is considered when respective components are identified with Grade 2b lucency (see below) or a shift in position (see previous section) between postoperative radiographs (implants at risk of failure based on radiographic outcome).

##### Specifications :

RLL are documented according to their presence or absence, location and thickness, separately for the humeral and glenoid components. The humeral component is further divided into metaphysis and diaphysis according to the surgical neck of the humerus (visible on standard radiographs).

Within each of these locations (as appropriate for various prosthesis types), the severity of RLL occurrence is graded as follows:

Grade 0 : None (no clear sign of RLL)

Grade 1 : Incomplete RLL (radiolucency not all around the implant)

- a. no line reaching 1.5mm in width
- b. at least one RLL reaching 1.5mm or more in width

Grade 2 : Complete radiolucency around the implant

- a. not reaching 1.5mm in width
- b. reaching 1.5mm or more in width (loosening)

**Do you agree with this definition, specifications and terminology (including changes)?**

☐ Yes ☐ No

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**Comment or alternative suggestion**

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  
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Page 5 of 21

### Radiographic parameters (3)

#### Signs of shoulder instability

*Based on a proposal by Dr. Philipp Moroder (Charité Universitätsmedizin Berlin, Germany)*

**91% (61/67) of participants agreed about the proposed definition, specifications and terminology**

Attachment:  [DelphiSurvey02-03-ImagingDef-ShoulderInstability.pdf](#) (0.1 MB)

**Definition of terms :** Shoulder instability refers to a loss of alignment of the articulating surface of the humeral component with the articulating surface of its joint partner.

**Specifications :**

- Static instability: non-arm position-dependent eccentric misalignment with residual contact visible on standard radiographs.
- Dislocation: non-arm position-dependent complete loss of contact visible on standard radiographs.

When present, the direction of instability or dislocation is noted from the AP view (superior / inferior) as well as from the axillary view (anterior / posterior).

**Do you agree with this definition, specifications and terminology  
(including changes)?**

☐ Yes ☐ No

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[Expand](#)

[<< Previous Page](#)

[Next Page >>](#)

[Save & Return Later](#)



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  


Page 6 of 21

### Radiographic parameters (4)

#### Bone resorption / Bone formation

*Based on a proposal by Dr. Simon Lambert (University College London Hospital, London, UK)*

**97% (64/66) of participants agreed about the proposed definition, specifications and terminology**

Attachment:  [DelphiSurvey02-04-ImagingDef-BoneResorption\\_Formation.pdf](#) (0.11 MB)

**Definition :** Bone resorption: the progressive disappearance of bone from the humerus and/or scapula following SA when compared to the immediate post-operative condition.

Bone formation: the progressive apposition of bone on or in the humerus and/or scapula following SA when compared to the immediate post-operative condition, more than that required for stable integration of the prosthesis.

- Orthotopic bone formation (ossification) is bone formation within the confines of the bone including the periosteum: bone is formed within tissue that is destined to be or become bone under normal healing or loading conditions.
- Heterotopic bone formation (ossification) is a subset of excess bone formation within or between tissues that is not destined to be or become bone under normal healing or loading conditions.

**Specifications :**

Bone region-based description of periprosthetic occurrence / extent of bone resorption / formation:

- Humeral side: further divided into metaphysis and diaphysis according to the surgical neck of the humerus (visible on standard radiographs). When located above the surgical neck, the involvement of the calcar region and/or the tuberosities is documented.
- Glenoid side (without further division)

Heterotopic bone formation is classified according to the Brooker classification.

**Scapular notching :** Scapular notching specific to reverse SA is a form of glenoid-side bone resorption and is classified according to the Nerot-Sirveaux classification.

**94% (60/64) of participants agreed about the proposed definition, specification and terminology**

Attachment:  [DelphiSurvey02-05-ImagingDef-Scapular\\_notching.pdf](#) (0.12 MB)

**Do you agree with this definition, specifications and terminology  
(including changes)?**

☐ Yes ☐ No

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**Comment or alternative suggestion**

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  
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Page 7 of 21

### Radiographic parameters (5)

#### Wear of the implant articular surfaces

*Based on a proposal by Dr. Richard Page (Deakin University, Burwood, VIC, Australia)*

**97% (63/65) of participants agreed about the proposed definition, specifications and terminology**

Attachment:  [DelphiSurvey02-06-ImagingDef-Wear\\_ArtSurface.pdf](#) (0.11 MB)

**Definition :** Damage, erosion or loss of surface material of an implant over time, usually due to friction. Biologically active particles generate an inflammatory response including osteolysis that may result in bone resorption and/or loss of fixation of the implant.

**Specifications :** Eccentric / Concentric

**Do you agree with this definition, specifications and terminology  
(including changes)?**

☐ Yes ☐ No

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**Comment or alternative suggestion**

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<< Previous Page

Next Page >>

Save & Return Later



## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  


Page 8 of 21

### Radiographic parameters (6)

**Other radiographic parameters were supported and therefore added to the core set as suggested below.**

Notes: Rotator cuff integrity was suggested, however, not further considered as it cannot be reliably documented using standard radiographs other than via proxy parameters such as humeral head migration in asymptomatic patients.

Attachment:  [DelphiSurvey02-07-ImagingDef-OtherParameters.pdf](#) (0.08 MB)

#### Fractures around the implant

**Specifications :**

Humeral fracture:

- Tubercula
  - Sub-capital, at the surgical neck (stemless prosthesis)
  - Diaphysis spiral / transverse (shaft prosthesis)
  - Distal (below the shaft)
- Scapula fracture: glenoid / scapula spine / acromion / coracoid

Notes:

- A number of classification systems for peri-prosthetic humeral fractures were in use (Campbell et al, Wright and Cofield, Groh et al, Worland et al), however they were developed for shaft prosthesis to support further treatment algorithms\*. This is beyond the objective of this monitoring process, which should primarily document the fracture location.

- Peri-prosthetic humeral fractures may occur because of trauma or loosening of the implant\*\*.

\* Kirchhoff C, Kirchhoff S, Biberthaler P. [Classification of periprosthetic shoulder fractures]. *Der Unfallchirurg* 2016;119:264-272.

\*\*Andersen JR, Williams CD, Cain R, Mighell M, Frankle M. Surgically treated humeral shaft fractures following shoulder arthroplasty. *The Journal of bone and joint surgery American volume* 2013;95:9-18.

#### Osteochondral erosions (as another form of bone resorption presented in a previous section)

**Definition :** Abrasion of bone and/or cartilage caused by friction with a prosthesis component.

**Specifications :**

Glenoid erosion (only for hemi-arthroplasty) :

- Eccentric : occurrence of localized glenoid rim erosion
- Concentric : humeral head centered without localized glenoid rim erosion

Erosion of the acromion (only for anatomical hemi and total arthroplasty): concave deformity of the acromion undersurface (acetabularization).

#### Implant breakage / disassembly

**Definitions :**

- Implant breakage : one part of the prosthesis is broken
- Implant disassembly : noticeable change of the relative position of the various parts of an implant humeral or glenoidal component

**Specifications :** Humeral side / Scapula side

**Do you agree with these additional definitions, specifications and terminology?**

☐ Yes ☐ No

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**Comment or alternative suggestion**

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[<< Previous Page](#)

[Next Page >>](#)

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## Consensus development of a core list of shoulder arthroplasty complications (survey 3)

Resize font:  
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Page 9 of 21

### Radiographic monitoring (7)

#### Radiographic views, quality criteria and schedule

*Based on the initial proposal by Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)*

**75% (49/65) of participants agreed about the proposed minimum radiographic set and schedule**

Attachment:  [DelphiSurvey02-08-ImagingDef-Radiographs.pdf](#) (0.09 MB)

**Standard radiographic views** (fluoroscopic positioning is recommended) :

- True anteroposterior view in 0° abduction and in neutral position (i.e. neutral to the plane of the scapula)
- Axillary view in 90° abduction with the humerus in linear alignment with the scapular body (i.e. perpendicular to the glenoid) or Y-view (e.g. if axillary view cannot be obtained due to limited abduction capacity).

**Monitoring time frame** : First set of radiographs within the first six weeks after implantation, a second set at three months and a third set 12 months after implantation.

**Do you agree with this proposed minimum radiographic set and timeline?**

☐ Yes ☐ No

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**Comment or alternative suggestion**

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<< Previous Page

Next Page >>

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Consensus development of a core list of shoulder arthroplasty complications  
(survey 3)

Resize font:  
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Page 21 of 21

Many thanks!

Do you have any general comment(s)?

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<< Previous Page

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## **File 5: SA Monitoring Consensus Panel**

### **SA Monitoring Consensus Panel (98 participants in alphabetical order):**

Äärmaa Ville, MD, Turku University Hospital, Turku, Finland  
Alta Tjarco D., MD PhD, Spaarne Gasthuis, Haarlem/Hoofddorp, Netherlands  
Amaral Marcus Vinicius, MD Msc, Instituto Nacional de Traumatologia e Ortopedia, Rio de Janeiro, Brazil  
Armstrong Alison, MD, University Hospitals of Leicester NHS Trust, Leicester, Leicestershire, UK  
Arthur van Noort, MD PhD, Spaarne Hospital, Hoofddorp, Noord Holland, Netherlands  
Bale Steve, MD, Wrightington Hospital, Wrightington, UK  
Beyth Shaul, MD PhD, Hadassah Medical Center, Jerusalem, Israel  
Bischof Andreas, MD, Berit Klinik, Speicher, AR, Switzerland  
Bokor Desmond J., MD, Faculty of Medicine & Health Sciences, Macquarie University, Sydney, NSW, Australia  
Borroni Mario, MD, Humanitas Clinical and Research Center IRCCS, Rozzano (MI), Italy  
Brorson Stig, MD PhD DMSc, Zealand University Hospital, University of Copenhagen, Copenhagen, Denmark  
Brownson Peter, DM FRCS ED FRCS (Tr & Orth), Royal Liverpool Hospital, Liverpool, UK  
Buchmann Stefan, MD, Orthopädisches Fachzentrum Weilheim, Weilheim, Germany  
Buess Eduard, MD, Shouldercare clinic, Berne, Switzerland  
Cass Benjamin, MD, Royal North Shore Hospital, Sydney, NSW, Australia  
Cormac Kelly, MD, Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry, Shropshire, UK  
De Cupis Vincenzo, MD, ICOT, Latina (LT), Italy  
Debeer Philippe, MD PhD, University Hospitals Leuven, Leuven, Belgium  
Derek F.P. van Deurzen, MD, Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands  
Dillon Mark T., MD, The Permanente Medical Group, Kaiser Permanente, Sacramento, CA, USA  
Durchholz Holger, MD, Klinik-Gut, St. Moritz, Switzerland  
Ekelund Anders, MD, PhD, Dep of Orthopaedics, Capió St Görans Hospital, Stockholm, Sweden  
Etzner Mikael, MD, Dep of Orthopaedics Sjukhuset i Varberg, Varberg, Sweden  
Flury Matthias, MD, Zentrum für Orthopädie & Neurochirurgie, In-Motion, Wallisellen, Switzerland  
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Georgousis Harry, MD PhD, St. Joseph Hospital, KKRH - Contillia Group, Essen, Germany  
Gerber-Popp Ariane, MD, Kantonsspital Baselland, Basel, Switzerland  
Gulyás Károly, MD, Péterfy Sándor Hospital and Trauma Center, Budapest, Hungary  
Henry Patrick, MD, University of Toronto, Toronto, ON, Canada



Hertel Ralph, MD, Lindenhofspital, Berne, Switzerland  
Heuberer Philipp, MD, Krankenhaus der Barmherzigen Schwestern Wien, Vienna, Austria  
Holland Philip, MD, The James Cook University Hospital, Middlesbrough, Cleveland, UK  
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Kent Matthew, MD, Royal Liverpool Hospital, Liverpool, UK  
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Lädemann Alexandre, MD, University of Geneva, Geneva, Switzerland  
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Rosso Claudio, MD MSc, ARTHRO Medics Corp and University of Basel, Basel, Switzerland  
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Ruiz-Iban Miguel A., MD PhD, Hospital Universitario Ramón y Cajal, Madrid, Spain  
Salomonsson Björn, MD PhD, Karolinska Institutet Danderyds Sjukhus AB, Stockholm, Sweden  
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Savoie Felix H., MD, Department of Orthopaedic Surgery, Tulane University, New Orleans, LA, USA  
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Scheibel Markus, MD, Schulthess Klinik, Zurich, Switzerland  
Schwyzer Hans-Kaspar, MD, Schulthess Klinik, Zurich, Switzerland  
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Spormann Christoph, MD, Endoclinic Zurich, Zurich, Switzerland  
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Thillemann Theis, MD PhD, Aarhus University Hospital, Aarhus, Denmark  
Throckmorton Thomas (Quin), MD, University of Tennessee-Campbell Clinic, Memphis, TN, USA  
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## **File 6: SA Radiological Monitoring v1.0 - Delphi 01 survey results – June 2017**

SA Radiological Monitoring v1.0

Core list of radiological parameters for shoulder arthroplasty (SA) monitoring

Delphi 01 survey results

June 2017



## Project objective, concept and participation

The primary objective of this project is to define a core set of untoward events occurring during and after shoulder arthroplasty (SA) along with their terms and definitions, which should be documented in clinical studies, registers and routine care.

*Note:* This online survey is the first as part of a modified Delphi exercise, which will possibly include up to 3 surveys in total. It is based on a similar development that was recently completed for events of arthroscopic rotator cuff repair\*

\*Audigé L, Flury M, Müller AM, ARCR CES Consensus Panel, Durchholz H. Complications associated with arthroscopic rotator cuff tear repair: definition of a core event set by Delphi consensus process. *Journal of Shoulder and Elbow Surgery* 2016; 25: 1907–1917.

doi: 10.1016/j.jse.2016.04.036

### Conceptual development of the core set

This initial survey is based on a conceptual framework from previous experience in the field of arthroscopic rotator cuff repair as well as new considerations resulting from a literature review of shoulder arthroplasty (SA) complication and event terms. In the field of SA, many imaging parameters can be documented without symptoms, therefore we propose to address this issue by the following distinction:

1- Observations on imaging at follow-up controls including radiolucency around an implant, bone resorption, scapular notching, stress shielding, ....

2- Local (regional) untoward events affecting the treated shoulder that distinguish further intraoperative and postoperative events, and are considered in a hierarchical structure involving event groups and specifications.

*Note:*

Nonlocal events affecting the rest of the body are addressed in a separate project because they are not specific to the field of SA. General consensus is being searched globally for all orthopedic interventions.

There were 90 participants including 73 (79%) who completed the survey

Distribution per level of experience

Annual number of SA*	Number of years of surgical experience in orthopedics				Total
	1-5	>5-10	>10-20	>20	
1-20	0	4	5	3	12
>20-50	1	5	13	15	34
>50-100	0	3	12	15	30
>100	0	1	7	6	14
Total	1	13	37	39	90

Concept and developmental process: 99% agreement (89/90)

### Comments

“Observations on imaging - the first category - should include note on WHEN this change appeared. i.e. was poor glenosphere tilt or other problem picked up in the FIRST post-operative image or is the recorded abnormality presenting later - such as NOTCHING or heterotopic ossification. “

“Also nonlocal events, like venous thrombosis non necessarily in proximity of the surgical site, or pulmonary embolism, should be considered as specific complications of SA”

“There may be some asymptomatic problems which also determine treatment to prevent future problems such as advancing lucency contributing to a decision to revise or investigate for infection even if it is not symptomatic as increasing bone loss would be detrimental to next surgery success.”



“Neurogenic complications may affect the distal extremity and therefore term 'local' may not be appropriate.”

## Imaging parameters (1)

i.e. systematic controls conducted independently on the occurrence of symptomatic event(s).

Which of the following imaging technique(s) should be routinely used to monitor shoulder arthroplasties?

Imaging technique(s)	Other images	n	%
Radiographs		75	83.3
Radiographs & CT		5	5.6
Radiographs & CT & MRI		1	
Radiographs & CT & MRI & Other	Spect CT	1	
Radiographs & CT & Other	CT arthrogram	1	
Radiographs & CT & Other	Consider RSA studies	1	
Radiographs & CT & Scintigraphy		1	
Radiographs & MRI		1	
Radiographs & Other	Ultrasound	2	
Unknown		2	
		90	

Which of the following imaging parameters should be considered as part of an observation protocol?

Imaging parameters	n	%
Radiolucency	83	92.2
Loosening	84	93.3
Implant migration	86	95.6
Signs of instability	80	88.9
Bony formation	57	63.3
Bone resorption	78	86.7
Stress shielding	69	76.7
Scapular notching	82	91.1
Implant wear	70	77.8
Arthritis	40	44.4
Other parameter(s)	8	8.9

### *Other parameter(s)*

“Scapula / Acromion”

“Status of rotator cuff”

“Implant failure - e.g. breakage”

“Implant breakage, implant dissociation, Fractures/healing (acromion, scapula, humerus, unhealed osteotomy, or tubercle migration, Glenoid wear”

“Stress reactions (acromion in RSA)”

“Implant failure (Breakage), periprosthetic fracture”

“(Stress) fractures”

“Acromial fracture or fragmentation”



*Comments or suggestions*

“Rx should only be used for asymptomatic patients. If symptoms arise, all of the above may be possible.”

“Stress fracture.”

“As a practical clinical evaluation, radiographs are clearly more economical than CT. When problems occur we would then go to second-line imaging, including CT, scintigraphy, MARS etc, to further define the degree of the problem. Implant migration can only be accurately measured with interval qCT or RSP, although radiographs will show gross migration.”

“Evidence of rotator cuff failure”

“Implant breakage, Implant dissociation, Fractures (acromion, scapula, humerus), Healing, (unhealed osteotomy, or tubercle migration after reattachment). Glenoid wear in hemiarthroplasty. And other possible observations on plain radiographs”

“Adequacy of reconstruction”

“Implant integrity (breaking,...)”

“CT - USED WHEN YOU NEED TO AN INVESTIGATION”

“Acromion stress fractures are sometimes seen in reverse shoulders”

“To my knowledge there is still no consensus about the definition where radiolucency ends and where osteolysis begins. Furthermore when is an implant loose and what is the difference between bone resorption and osteolysis? Unfortunately these are very soft parameters that may confuse more than clarify. Therefore, prior to implementation an agreement about definition should be reached. Implant wear can only be observed indirectly on xray or ct in reduction of joint space. True a.p. Images should be demanded, especially to detect instability.”

“CT scans would be very useful to monitor implants. However costs may limit the use of this for routine monitoring.”

“The item ' Implant wear' will be difficult to describe on the basis of radiographs. Therefore, I suggest to use joint line asymmetry instead of implant wear..”

“Most of these parameters should be observed regularly (yearly)”

“Periprosthetic fracture complications require radiographic follow-up on osseous healing CT must be easily available as a secondary investigation”

“Implant fracture”



## Imaging parameters (2)

At which time points should imaging parameters be systematically monitored for all patients?

### Within the first 5 years after SA

Time point response profiles	Other time points	n
12mo		13
12mo, 2y		1
12mo, 2y, 4y		1
12mo, 2y, 5y		1
12mo, 3y, 5y		1
12mo, 5y, other	Immediate post surgery images	1
2y		2
2y, 5y		3
3mo		4
3mo, 12mo		2
3mo, 12mo, 2y, 3y, 4y, 5y		2
3mo, 12mo, 2y, 3y, 5y		3
3mo, 12mo, 2y, 4y		1
3mo, 12mo, 2y, 5y		5
3mo, 12mo, 3y, 5y		3
3mo, 12mo, 3y, 5y, other	10, 15, 20, 25 years and so on...	1
3mo, 12mo, 5y		5
3mo, 2y, 4y		1
3mo, 2y, 5y		1
3mo, 5y, other	or if symptoms change	1
3mo, 6mo, 12mo, 2y		2
3mo, 6mo, 12mo, 2y, 3y, 4y, 5y		7
3mo, 6mo, 12mo, 2y, 3y, 5y		1
3mo, 6mo, 12mo, 2y, 4y		1
3mo, 6mo, 12mo, 2y, 5y		4
3mo, 6mo, 12mo, 3y, 5y		2
3mo, 6mo, 12mo, 5y		2
6mo		2
6mo, 12mo, 2y, 3y, 4y, 5y		1
6mo, 12mo, 2y, 5y		6
6mo, 12mo, 3y, 5y		2
6mo, 12mo, 3y, 5y, other	Whenever patients have new symptoms related to the joint	1
6mo, 2y, 5y		3
other	one year, then if all is well more than 2 years - I wonder if it could be left next until 5 years	1
Unknown		3



Time points	n	%
Never	0	-
3 months	48	54.5
6 months	34	38.6
12 months	69	78.4
2 years	46	52.3
3 years	24	27.3
4 years	14	15.9
5 years	56	63.6
Other time	5	5.7

#### More than 5 years after SA (n,%)

Time points	n (%)
Never	8 (9)
Every year	9 (11)
Every 2 years	23 (27)
Every 3 years	7 (8)
Every 5 years	28 (33)
Every 10 years	1 (1)
Other frequency	9 (11)

About 7-8 years I think it should be every 2 years and then if anything untoward is seen then more frequently

4, 7, 10 years, then every two years

At 10 years then every 10 years

Whenever patients have symptoms related to the joint (n=6\*)

\* decision for intervention not dictated by radiological appearances

84 surgeons (97%) agreed that imaging parameters be documented in addition to motion and strength in all patients reporting shoulder pain and/or loss of function after SA

#### *Comments or suggestions*

“After 5 years it should be if there is a clinical complaint and problem”

“Changed protocol from I year CT to limited CTs no plain X-rays as part of research project : Time zero, 3 6, 12 and 24 months only”

“Include CT or US depending on whether cuff failure suspected”

“Shoulder pain or loss of function should alert to a problem with the implant. In this situation, patient need an new imaging, that can be an X-ray or other depending of the clinical diagnosis”

“Since this is commonly due to rotator cuff fatigue/degeneration, we have to develop a clinically-convenient methodology of assessing cuff functional competence. Ultrasound is not always easy to deploy with an arthroplasty. CT with arthrogram may be the 'gold' choice, but is not readily available, nor easily affordable.”

“Imaging parameters should be documented also yearly, within 2 years after SA, if clinical symptoms and radiographic alterations are rising”

“Baseline X-ray imaging Consideration of cuff imaging (USG) depending on examination findings”



“The time for imaging in a lifelong situation must be that it is done whenever there are symptoms that require an investigation. But with new designs and implants a structured follow up is needed for safety reasons in a set of patients that is followed.

“Routine follow up not indicated if the patient is asymptomatic. One follow up with radiographs at 3-6 months sufficient. Patient recommended to contact if symptoms develops. Asymptomatic radiographic findings do not result in a revision.

“In my clinical practice I usually advise the patient to come back if he feels a change with increased symptoms

“You should have the images to compare”

“No routine follow-up. But if patient experiences pain/decrease in function in the affected shoulder he/she should have an X-ray and visit to the clinic.”

“Scintigraphy and blood samples in patients with pain”

“Initial post-operative images should be of good quality or repeated at 6 weeks post-operatively when pain and position for the images will be better. Good quality post-operative images are very important as a bench-mark. BESS guidelines = 6 weeks, 1 year and 2 year follow-up with scoring and radiographs. Discharged to General Practitioner with advice to get radiographs at years 5 and 10 post-operatively.”

“This is quite arbitrary and clearly if abnormalities are seen the label of frequency of observation needs to increase”

“A postoperative x-ray and clinical follow-up is mandatory for all patients. Thereafter if everything is OK, no further routine control of asymptomatic patients is needed. The patients must be instructed to contact the clinic in case there is a problem concerning the operated shoulder.”

## Imaging parameter definitions :

For each of the imaging parameters previously selected as important by respondents, we asked about the most important feature(s) that should be taken into account and/or which scientific reference(s) should be considered essential for the formulation of a definition.

An example with radiolucency was presented as to how a definition could be formulated. We suggested that future definitions should be sufficiently simple to apply to most (if not all) prosthesis types. It is therefore important to specify if suggestions apply to all or specific prosthesis type(s).

## Radiolucency around the implant

### *Summary of most-relevant responses*

- Lucent lines at bone-implant interface : proposal is ok, but add “progression”
- If symptom (which ones?), repeated radiograph to detect implant migration or progress of zones.
- Progression of RL is the most important feature, independent of location
- Consider the Mayo Clinic system
- “It would be good to find an implant independent description.”
- 2 specific comprehensive comments, which can be used to build a definition:
  - “Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant interface and is evaluated using plane radiographs according to their presence or absence, location and thickness. The humeral and glenoid components are divided into radiographic zones specific to each device (e.g. using a shaft prosthesis, the humerus is divided into 8 zones\*). The maximum thickness of the lines is measured to within 0.5 mm. \*Sperling, J.W., Cofield, R.H., O’Driscoll, S.W., Torchia, M.E., Rowland, C.M.: Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg, 9(6): 507-513, 2000”
  - “Reverse: Any radiolucent lines around the glenoid screws, around the peg or below the baseplate: classified according to their width (< 2 mm or ≥ 2 mm). Humeral radiolucent lines: assessed in seven zones according to the classification of Gruen et al adapted to the shoulder, classified according to width (< 2 mm or ≥ 2 mm). (Melis et al, 2011)  
Anatomic: Based on the method described by Molé et al.(1999) A numeric value was applied to each of the 5 zones surrounding the glenoid implant according to the thickness of the RLL. RLLs were scored on a scale of 0 to 15. A score >10 points indicates definite radiologic loosening of the MB implant.”



- Whether related to uncemented or cemented implant ? same zones for cemented and non cemented, but in no cemented it is most relevant to coated areas of implant.
- Suggested references
  - Sperling, J.W., Cofield, R.H., O'Driscoll, S.W., Torchia, M.E., Rowland, C.M.: Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg, 9(6): 507-513, 2000
  - Vavken P, Sadoghi P, von Keudell A, Rosso C, Valderrabano V, Muller AM. Rates of radiolucency and loosening after total shoulder arthroplasty with pegged or keeled glenoid components. J Bone Joint Surg Am 2013;95:215-221. doi: 10.2106/JBJS.L.00286
  - Lazarus MD, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am. 2002;84:1174-1182.
  - Kasten et al Mid term survivorship analysis of a shoulder replacement with a keeled glenoid and a modern cementing technique JBJS 92-B
  - Reverse SA: Melis B1, DeFranco M, Lädermann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.
  - Anatomic SA: D. Molé, O. Roche, N. Riand, C. Lévigne, G. Walch Cemented glenoid component: results in osteoarthritis and rheumatoid arthritis G. Walch, P. Boileau (Eds.), Shoulder arthroplasty, Springer, New York (1999), pp. 163-171 and <http://dx.doi.org/10.1016/j.jse.2015.02.012>

#### *Original unsorted open-text responses*

"I fear that my response are out of sync with my colleagues as we are collecting data is a comprehensive research exercise and moved away from the normal systems. I wonder if I should be excluded as I fear I might imbalance your study. I am quite happy to discuss what we currently do"

"Progression on serial xrays"

"Lucency according to zones"

"To evaluate the progression of the radiolucency"

"Bone-implant interface"

"Continuous with osteolysis (infection)/continuous without osteolysis (mechanical loosening, ? low-grade infection) / discontinuous with osteolysis (material-related osteolysis) / discontinuous without osteolysis/fracture"

"We use the mayo classification systems for all these parameters"

"No better definition than as described above."

"Site of radiolucency and the size of the lucency (<1mm, 1-2mm, >2mm)"

"The radiolucency definition is correct but radiolucency progression is essential"

"Occurrence of and enlargement of radiolucencies"

"Lucent lines around implant "

"Progressing or non-progressing lines"

"Site, size and width Evidence of progression compared to base line"

"Development of lucent lines between bone and implant"

"Agree with above"

"Number of zones with RLL and the largest zone in mm. If symptom, repeated radiograph to detect implant migration or progress of zones."

"Location, thickness, progression, implant migration"

"Important if the patient has pain. Asymptomatic radiolucency neglected"

"Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant interface and is evaluated using plane radiographs according to their presence or absence, location and thickness. The humeral and glenoid components are divided into radiographic zones specific to each device (e.g. using a shaft prosthesis, the humerus is divided into 8 zones\*). The maximum thickness of the lines is measured to within 0.5 mm. \*Sperling, J.W., Cofield, R.H., O'Driscoll, S.W., Torchia, M.E., Rowland, C.M.: Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg, 9(6): 507-513, 2000"



“Mid-term survivorship analysis of a shoulder replacement with a keeled glenoid and a modern cementing technique  
Kasten et al JBJS 92-B”

“Radiolucency lines are evaluated using the Mayo Clinic parameters and should be observed if they are progressive in serial images, help to identify components loosening and migration

“It would be good to find an implant independent description. Perhaps focusing on the various zones in the bone (i.e. medial proximal humeral radiolucency or lateral distal humeral r ... etc.”

“I agree with the definition of Sperling et al.”

“I agree with the definition above”

“Longitudinal progression”

“We follow what is described in the paper above by Sperling et al

“obvious

“As stated in the artikel above, radiolucency is well described in zones, as a lucency in zone 1 , 7 and 8 can suggest partikel disease and lucency around the whole of the implant can suggest a infection”

“Reverse: Any radiolucent lines around the glenoid screws, around the peg or below the baseplate: classified according to their width (< 2 mm or □ 2 mm). Humeral radiolucent lines: assessed in seven zones according to the classification of Gruen et al adapted to the shoulder, classified according to width (< 2 mm or □ 2 mm). Melis B1, DeFranco M, Lädermann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926. Anatomic: Based on the method described by Molé et al. A numeric value was applied to each of the 5 zones surrounding the glenoid implant according to the thickness of the RLL. RLLs were scored on a scale of 0 to 15. A score >10 points indicates definite radiologic loosening of the MB implant. D. Molé, O. Roche, N. Riand, C. Lévine, G. Walch Cemented glenoid component: results in osteoarthritis and rheumatoid arthritis G. Walch, P. Boileau (Eds.), Shoulder arthroplasty, Springer, New York (1999), pp. 163-171 and <http://dx.doi.org/10.1016/j.jse.2015.02.012>”

“all implants”

“Progressive radiolucency is the only important feature, regardless of zone/location“

“Agree with the above definition but definitely recommend to encourage the use of controlled radiography (fluoroscopy guided) which allows for perfect orientation of the imaging plane in order to ensure to perfectly visualise the bone-implant interface. Any tilt of the image will make the RLL disappear.”

“Yes I agree with the above”

“Progression of lines”

“Reference for radiolucency around the glenoid for all designs: Lazarus MD1, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am. 2002 Jul;84-A(7):1174-82”

“I would just refer to current literature, like the one cited above”

“It could be defined on radiographs of >1 mm in any zones on bone implant interface when compared to original radiograph. If there is original lucency and it stays same it should not be taken into account.”

“Whether related to uncemented or cemented implant. Progression of radiolucency with time. Site of the radiolucency and its relationship to stability, rotation and potential gradual or sudden failure mechanisms. Relationship to symptoms, pain, function or not. Mileti et al JSES 13:492-498, 2004. Sanchez-Sotelo J Arthroplasty 16: 180-187,2001”

“Same zones for cemented and non cemented. More relevance to all zones in cemented but no cemented it is most relevant to coated areas of implant. Not sure how this can be simplified”

“Rates of Radiolucency and Loosening After Total Shoulder ...

[https://www.researchgate.net/.../235416207\\_Rates\\_of\\_Radiolucency\\_and\\_Loosening\\_A...](https://www.researchgate.net/.../235416207_Rates_of_Radiolucency_and_Loosening_A...) 17 Oct 2016 - Official Full-Text Publication: Rates of Radiolucency and Loosening After Total Shoulder Arthroplasty with Pegged or Keeled Glenoid.”

“Lazarus MD, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am. 2002;84:1174-1182.”

“Short description of the extent (mm) and anatomic zone of occurrence according to the definition of Sperling et al.”

“Only important in symptomatic patients - suspicion of loosening (infection)”



## Loosening / osteolysis

### *Summary of most-relevant responses*

- Document time and location of osteolysis
  - “Usually most significant when seen at the end of implants”
  - “Osteolysis around screws in a reverse can suggest infection”
- Loosening
  - Macroscopic change in the relationship between one implant component and surrounding bone osteolysis .... Not the same as osteolysis !
  - Implies occurring motion. No contact with bone.
  - Implant migration or RLL in more than half of the pre-defined radiographic zones
  - Progressive and extensive widening of interfaces between bone-cement, bone-prosthesis or cement-prosthesis. Fragmentation or fracture of cement Migration/subsidence of prosthetic components Bead shedding in porous-coated prosthesis <https://www.cedars-sinai.edu/Patients/Programs-and-Services/Imaging-Center/For-Physicians/Musculoskeletal-Radiology/Exhibits-and-Presentations/Shoulder-Arthroplasty/Aseptic-Loosening.aspx>
  - Loosening glenoid: considered to be present if the glenoid component had migrated, as demonstrated by shift, tilt or subsidence, or if complete radiolucency  $\geq 2$  mm was present in each zone.  
Loosening humeral component: defined as displacement of the humeral component between the time of the initial post-operative radiograph and the most recent follow-up, or if radiolucency  $\geq 2$ mm present in more than three zones. (Melis et al. 2011)
- Osteolysis
  - Radiolucency more than 0,5mm all around the implant.
  - Osteolysis = bone loss around the implant
  - Periprosthetic bone loss visible as complete disappearance, partial disappearance or loss of bone mineral density
  - “An osteolysis grading system is needed.” .. e.g. Thomas Gregory's score\$
  - Loss of supporting bone tissue adjacent to either glenoid or humeral components of the prosthesis as evident by plain radiographs or by CT scan and by comparison to baseline images. (Yian et al. 2005)
- We may define RLL & sign of osteolysis, but loosening only in relation to migration (“proof of loosening is only given, if implant migration is undoubtedly detected”). This means that if RLL or osteolysis progress over a given threshold, there may be an indication to either increase monitoring to detect migration in time (considering still lack of symptoms?) or revise.
- References:
  - Melis B1, DeFranco M, Lädemann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.
  - Yian EH, Werner CM, Nyffeler RW, Pfirrmann CW, Ramappa A, Sukthankar A, Gerber C Radiographic and computed tomography analysis of cemented pegged polyethylene glenoid components in total shoulder replacement. J Bone Joint Surg Am. 2005 Sep; 87(9):1928-36.
  - Matsen et al Glenoid component failure in total shoulder Arthroplasty JBJS Am 2008;90:885-896
  - Raiss et al Radiographic changes around humeral components in shoulder arthroplasty JBJS Am 2014
  - Wirth MA, Agrawal CM, Mabrey JD, Dean DD, Blanchard CR, Miller MA, Rockwood CA Jr. Isolation and characterization of polyethylene wear debris associated with osteolysis following total shoulder arthroplasty. J Bone Joint Surg Am. 1999 Jan;81(1):29-37.
  - adapted classification by Gruen which was initially developed for total hip arthroplasty: Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. Clin Orthop Relat Res 1979;141:17-27.



*Original unsorted open-text responses*

“Distance and diameter of cysts and osteolytic zones. I do not know a proper quantification method, but have hardly ever the need for it.”

“An osteolysis grading system is needed. Frequently this is reported as  $RLL > 2\text{mm}$  when in some case there may be 3cm bone loss this classification may have impact on revision”

“Use Thomas Gregory's score”

“Progression on serial X-rays”

“Clearly important to document loosening direction”

“The time of the osteolysis”

“Around the implant”

“Same”

“Glenoid components can fail as a result of their inability to replicate essential properties of the normal glenoid articular surface to achieve durable fixation to the underlying bone, to withstand repeated eccentric loads and glenohumeral translation, and to resist wear and deformation. Bone resorption can be observed on X-rays: radiolucency, resorption, loosening of change of trabecular pattern.”

“Usually most significant when seen at the end of implants (e.g. set of humeral shaft, medial tip of gleaned poly peg)”

“Loosening definitively related to migration osteolysis also related strongly to radiolucency I would consider avoiding duplicities”

“Change of the position of the component”

“Hollowed out area of prosthetic motion or loss of bone from one image set to next set “

“Same as above Need to differentiate whether seen on XR or CT”

“Loosening = macroscopic change in the relationship between one implant component and surrounding bone  
 osteolysis = area of bone resorption usually with cortical thinning”

“Primarily on the stem, you may be able to see resorption of bone from the area around the calcar”

“If symptom, repeated radiograph to detect implant migration or progress of osteolysis Obvious loosening on radiographs is essential findings.”

“Location, timing from surgery, progression”

“Radiolucency more than 0,5mm all around the implant, evaluated on plane radiographs Osteolysis is bone loss around the implant on plan radiographs”

“Important to detect. If the patient has symptoms revision may be indicated”

“Osteolysis refers to loss of supporting bone tissue adjacent to either glenoid or humeral components of the prosthesis as evident by plain radiographs or by CT scan and by comparison to baseline images. Radiographic and computed tomography analysis of cemented pegged polyethylene glenoid components in total shoulder replacement. Yian EH, Werner CM, Nyffeler RW, Pfirrmann CW, Ramappa A, Sukthakar A, Gerber C J Bone Joint Surg Am. 2005 Sep; 87(9):1928-36.”

“Glenoid component failure in total shoulder Arthroplasty Matsen et al JBJS Am 2008;90:885-896 Radiographic changes around humeral components in shoulder arthroplasty Raiss et al JBJS Am 2014 “

“Isolation and characterization of polyethylene wear debris associated with osteolysis following total shoulder arthroplasty. Wirth MA, Agrawal CM, Mabrey JD, Dean DD, Blanchard CR, Miller MA, Rockwood CA Jr. J Bone Joint Surg Am. 1999 Jan;81(1):29-37.”

“Signs that the implants could have motion for septic or aseptic reasons and need to be revised.”

“Loosening implies occurring motion. This implies that there is no bony contact to the implant anymore.”

“Proof of loosening is only given, if implant migration is undoubtedly detected. suspicion of loosening is given if radiolucent lines progress over time or exceed 2mm.”

“2 or more zones”

“Need to be compared with the previous X-rays”

“Obvious”

“Osteolysis around screws in a reverse can suggest infection”



“Loosening: considered to be present if the glenoid component had migrated, as demonstrated by shift, tilt or subsidence, or if complete radiolucency  $\geq 2$  mm was present in each zone. Loosening: defined as displacement of the humeral component between the time of the initial post-operative radiograph and the most recent follow-up, or if radiolucency  $\geq 2$  mm present in more than three zones. Melis B1, DeFranco M, Lädermann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.”

“Description, all implants”

“Progression of lucency or osteolysis.”

“Loosening: Implant migration or RLL in more than half of the pre-defined radiographic zones Osteolysis: Periprosthetic bone loss visible as complete disappearance, partial disappearance or loss of bone mineral density”

“This is similar to the above. It usually progressive. It would need to be quantified in zone and magnitude.”

“Progression of lysis”

“For stem loosening, one should use the adapted classification by Gruen which was initially developed for total hip arthroplasty: Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. Clin Orthop Relat Res 1979;141:17-27.”

“Radiographic signs of loosening include: Progressive and extensive widening of interfaces between bone-cement, bone-prosthesis or cement-prosthesis. Fragmentation or fracture of cement Migration/subsidence of prosthetic components Bead shedding in porous-coated prosthesis

<https://www.cedars-sinai.edu/Patients/Programs-and-Services/Imaging-Center/For-Physicians/Musculoskeletal-Radiology/Exhibits-and-Presentations/Shoulder-Arthroplasty/Aseptic-Loosening.aspx>”

“Whether related to uncemented or cemented implant. Progression of radiolucency with time. Site of the loosening / osteolysis and its relationship to stability, rotation and potential gradual or sudden failure mechanisms. Relationship to symptoms, pain, function or not.”

“Short description of extent (in mm) and anatomic zone of occurrence.”

“Radiolucency all around the components does not mean Loosening!”

“Only important in symptomatic patients - suspicion of infection, poly wear, non-integration - revision potentially needed”

#### Implant migration (e.g. subsidence, tilt, shift) with regard to the adjoining bone

##### *Summary of most-relevant responses*

- Use standardized X-rays
- Timing
  - “Early migration can help the implant find a stable position and lead to secondary ingrowth. Late migration is a sign of loosening.”
  - Progression beyond first six months
- Migration of an implant = subsidence of one or more of the components.
  - Any change in position of the implant in relation to the surrounding bone
  - Any migration or change position of implant or cement with regards to original radiograph or progressive change in position of more than 2mm.
  - Changes in distance between fixed points can suggest migration
  - Clear mobilization of the implant from a set bony landmark / stem in relation to humeral canal
  - In serial radiograms, modifications of angular or linear relations between one implant component and surrounding bone
  - Subsidence= measured as the change in the vertical distance between the most superior aspect of the humeral component and the greater tuberosity.
  - Implant migration = dynamic change observed over time in the position of either humeral and or glenoid component relative to the host bone as measured by angles or distance on plain radiographs or CT scan images (Favard et al. 2012)
- References:
  - Favard L, Katz D, Colmar M, Benkalfate T, Thomazeau H, Emily S. Total shoulder arthroplasty - arthroplasty for glenohumeral arthropathies: results and complications after a minimum follow-up



- of 8 years according to the type of arthroplasty and etiology. Orthop Traumatol Surg Res. 2012 Jun;98(4 Suppl):S41-7. doi: 10.1016/j.otsr.2012.04.003. Epub 2012 May 12.
- Nuttall et al Comparison of micromovement of pegged versus keeled glenoid components using RSA
- Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G. Radiographic analysis of shoulder anatomical arthroplasty. Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021. Epub 2008 Sep 5.
- Mercer DM - 2011 A quantitative method for determining medial migration of the humeral.... [www.orthop.washington.edu/Portals/21/.../Shoulder%20.../Medial%20Wear%202.pdf](http://www.orthop.washington.edu/Portals/21/.../Shoulder%20.../Medial%20Wear%202.pdf)

### *Original unsorted open-text responses*

- “Difficult, depends strongly on the projection. More important on the glenoid side, particularly in RTSA.”
- “Use Marker based Ct and Karolinska software”
- “Progression on serial X-rays”
- “Should be measurable on standardised X-rays”
- “The presence of an implant migration is an categoric finding of a complication, other imaging as CT scan are necessary”
- “Related to the bone stock, comparison to the first postop X-ray.”
- “Same”
- “Migration of an implant is subsidence of one or more of the components. This can be related to loosening of an implant, or a radiological finding within the first year after implantation due to remodelling of bone. Migration might me measured on standardized X-rays. Changes in distance between fixed points can suggest migration. Scintigraphy can be useful to detect migration or loosening.”
- “Any shift of the components should be noted”
- “The presence of clear mobilization of the implant from a set bony landmark”
- “Movement up or down, in or out”
- “Change in position compared to base line Therefore need good base line imaging”
- “In serial radiograms, modifications of angular or linear relations between one implant component and surrounding bone”
- “Subsidence of the stem may be seen within the humeral canal. With regards to the glenoid, at least in total shoulder arthroplasty, there may be shifting of the radio opaque markers of the component.”
- “If symptom, repeated radiograph to detect implant migration or progress of tilt and shift. Obvious migration on radiographs is essential findings.”
- “Timing from surgery, association with radiolucency”
- “Implant migration is seen as a change of implant location in contrast to the previous radiographs”
- “Also important to detect in order to correlate symptoms or radiographic findings”
- “Implant migration is the dynamic change observed over time in the position of either humeral and/or glenoid component relative to the host bone as measured by angles or distance on plain radiographs or CT scan images. Orthop Traumatol Surg Res. 2012 Jun;98(4 Suppl):S41-7. doi: 10.1016/j.otsr.2012.04.003. Epub 2012 May 12. Total shoulder arthroplasty - arthroplasty for glenohumeral arthropathies: results and complications after a minimum follow-up of 8 years according to the type of arthroplasty and etiology. Favard L, Katz D, Colmar M, Benkalfate T, Thomazeau H, Emily S.”
- “Comparison of micro movement of pegged versus keeled glenoid components using RSA Nuttall et al“
- “Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021. Epub 2008 Sep 5. Radiographic analysis of shoulder anatomical arthroplasty. Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G.”
- “Another important parameter of septic or aseptic fail of the prosthesis”
- “Early migration can help the implant find a stable position and lead to secondary ingrowth. Slate migration is a sign of loosening.”
- “objectifiable implant migration proven in comparable radiological projections”
- “Progression beyond first six months”



“Need to be compared with the previous X-rays”

“Obvious”

“Implant migration has to be followed over time as a result of settling in first period and probably loosening over time may suggest other causes”

“Subsidence: measured as the change in the vertical distance between the most superior aspect of the humeral component and the greater tuberosity.”

“Preferably RSA, simpler methods may apply”

“Any movement of an implant is bad”

“Any change in position of the implant in relation to the surrounding bone”

“For the humeral head it is about medial migration(if hemiarthroplasty) this can be measured relative to the acromial lateral margin or the coracoid process. I have not seen much subsidence. For migration of the glenoid that is more difficult to quantify as many of the glenoids are all poly which makes them difficult to track. If they have a metal circle in them it is easier to spot loosening of the glenoid. For the reverses it is about tilt of the glenoid and scapula notching which may impinge on the lowest screw and then the glenoid starts to migrate. This would have to be measured relative to the coracoid”

“Tilt and bone loss”

“Glenoid subsidence is obvious on AP and axillary views. I do not know any classification system. Humeral sided subsidence may occur in stemless prosthesis, but almost never happens in TSAs with a stem.”

“Any migration or change position of implant or cement with regards to original radiograph or progressive change in position of more than 2mm.”

“Cemented or uncemented implant and progression. Failure mechanics”

“Difficult to measure on X-ray. Although this is important it needs weir stereotactic or CT imaging”

“A quantitative method for determining medial migration of the humeral ...

[www.orthop.washington.edu/Portals/21/.../Shoulder%20.../Medial%20Wear%202.pdf](http://www.orthop.washington.edu/Portals/21/.../Shoulder%20.../Medial%20Wear%202.pdf) by DM Mercer - 2011 - Cited by 13 - Related articles Hypothesis: Glenoid erosion and medial migration of the humeral head prosthesis have been observed after most types of shoulder arthroplasty.”

“Short description of extent (mm) in relation to the previous radiographic control.”

“Implant migration is given, when the thickness of radiolucency lines is bigger in some regions than in others. This is the beginning of implant migration.”

“Only important in symptomatic patients - component is loose and revision is needed”

### Signs of shoulder instability (e.g. dislocation, subluxation, head migration)

#### *Summary of most-relevant responses*

- “For reverse arthroplasty important with X-rays since dislocation is associated with very little pain”
- RC dysfunction= Asymmetric wear on poly and/or superior migration of head
- Partial or complete loss of articular relations (incongruency / an apparent abnormal positioning) between implant components, or in case of hemiarthroplasty between humeral component and glenoid
  - Need to standardize shoulder X-ray
    - axially and Bernageau views / Xrays in 2 planes ?
    - Position of the arm when taking the X-rays?
  - Needs to be relative to center of rotation of the humeral head vs that of the glenoid / Lack of centering
  - Direction of instability, progression of the superior head migration
  - Anatomic SA: AHD / anterior and Sub acromial space assessment
  - Early: stability of implant vs later: superior head migration
- Head migration: asymmetry or non-impaction of the glenosphere on the baseplate
- References:
  - Sanchez-Sotelo et al Instability after shoulder arthroplasty JBJS Am 2003 622-31
  - Current Concepts Review Complications of Total Shoulder Arthroplasty BY KAMAL I. BOHSALI, MD, MICHAEL A. WIRTH, MD, AND CHARLES A. ROCKWOOD JR., MD



*Original unsorted open-text responses*

- “Difficult, postoperatively inferior subluxation is common for days to weeks. Thereafter, strongly depending on activation of musculature and position. Would only use a yes/ no score.”
- “Acute change”
- “Indication for further imaging”
- “Direction of the instability, progression of the superior head migration”
- “No contact between the implants”
- “Anterior rotator interval lesions (including bicipital instability) posterior interval lesions (including deep surface partial tears of ISP/SSP junction)”
- “Same”
- “In cases of instability in SA, patients experience pain, clicking or other symptoms. Radiological findings can be normal, but subluxation of the prosthesis can be detected by clinical examination or X rays (ant/post/cranial subluxation).”
- “This is a clinical finding however may be evident with asymmetric wear on poly of superior migration of head indicative of cuff dysfunction”
- “Head migration is implant migration”
- “Lack of centering on axially and bernagqueau views”
- “Needs to be relative to centre of rotation of the humeral head vs that of the glenoid Consider direction - anteroposterior vs superior or inferior”
- “Partial or complete loss of articular relations between implant components, or in case of hemiarthroplasty between humeral component and glenoid”
- “In the early recovery phase, I am more interested in stability of the implant, especially on the AP view where you may be able to see the head slightly anterior on the glenoid. Later in the recovery process, I am more concerned with superior migration of the humeral head.”
- “If symptom, radiographs, Obvious dislocation or subluxation on radiographs is essential findings.”
- “Timing from surgery, amount, glenoid version”
- “Sign of instability seen on plan radiographs in two plan are an incongruence between the humeral head replacement and glenoid replacement or glenoid in case hemi arthroplasty as inferior, posterior or anterior subluxation or medial or cranial migration”
- “Important to help diagnose a secondary rotator cuff deficiency (anatomical arthroplasty). For reverse arthroplasty important with X-rays since dislocation is associated with very Little pain”
- “Shoulder instability refers to an apparent abnormal positioning of the glenoid component relative to the humeral component as evident by imaging studies.”
- “Instability after shoulder arthroplasty Sanchez-Sotelo et al JBJS Am 2003 622-31“
- “Head translation in respect to the glenoid is important. Consider that the position of the head on the glenoid might change according to the position of the arm or the activity to the muscles whilst taking the X-ray.”
- “Dislocation, decentering of head in axial plane, cranial or caudal head migration”
- “This should be evaluated by clinical exam and X-ray with regard to direction and grade of dislocation”
- “True axillary view, in doubt CT-Scan”
- “Shoulder instability should be described in direction of instability, problem is the different moment and views in which the x ray is taken”
- “Acromiohumeral Distance Decentering in the sagittal plane”
- “Head migration: asymmetry or non-impaction of the glenosphere on the baseplate”
- “All implants”
- “In my opinion a subluxed joint is not consistent with an optimal outcome.”
- “Any sign of static or dynamic eccentric position of the joint partners.”
- “History of dislocation. Serial X-rays showing the head migrating upwards to the acromion.(measure acromio-humeral distance)”



“Anterior and Sub acromial space assessment”

“In anatomic shoulder arthroplasty, one should measure the acromiohumeral distance as a sign of vertical Migration. In the axillary and lateral view, one should look for anterior Migration of the humeral head as a sign for subscapularis insufficiency”

“Obvious”

“Clinical ( pain and instability) and radiographic features ( subluxation = or > 50% migration and dislocation complete dissociation of two articular surfaces)”

“Cuff failure, implant wear, disassociation of poly with metal-back glenoids. Glenoid wear - native or implant. Implant malalignment”

“Need to standardise shoulder X-ray and how they are done. Define what is acceptable before trying to measure implant instability (assuming it is subtle). Simple way would be to relate to inferior glenoid for superior and coracoid for anterior”

“Current Concepts Review Complications of Total Shoulder Arthroplasty BY KAMAL I. BOHSALI, MD, MICHAEL A. WIRTH, MD, AND CHARLES A. ROCKWOOD JR., MD”

“Short description of direction related to the adjacent anatomic structures.”

“Dislocation is a radiological sign, the same is with subluxation,(also painful) Head Migration is a clinical and radiological sign (pain and change of head Position)”

“Only important in symptomatic patients - sign of rotator cuff insufficiency, revision to reverse potentially needed”

#### Bony formation (e.g. spurs, osteophytes)

##### *Summary of most-relevant responses*

- Definition items
  - Heterotypic ossification in the periarticular soft tissue
  - Local growth of reactive bone
  - Traction spurs, reactive bone formation in notching or peri-articular calcification.
  - Filling of spaces between the glenoid and the acromion and/or the humerus by aberrant bone tissue as seen in three oriented radiographs.
  - Bony excrescence: defined as a pillar scapular spur if it was absent pre-operatively and if it was in continuity with the bone of the scapular neck post-operatively
  - Ossifications: defined as heterotopic bone in the glenohumeral space if not in continuity with the scapular neck (Melis et al 2011)
- Relevance: signs of bone-prosthesis mechanical impingement (AE)
  - glenoid side mostly (RSA, Hemi)
- References:
  - Kjaersgaard-Andersen E Frich LK, Sojbjerg JO, Sneppen O: Heterotopic bone formation following total shoulder arthroplasty. J Arthroplasty 4:99, 1989
  - Boehm, Wallace, Neumann. Heterotopic ossification after primary shoulder arthroplasty JSES 2005 6-10
  - Sperling et al J Arthroplasty Heterotopic ossification after total shoulder arthroplasty 2000 179-82
  - Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G. Radiographic analysis of shoulder anatomical arthroplasty. Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021.
  - Melis B et al. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.

##### *Original unsorted open-text responses*

“Differentiate between - Heterotopic bone - Osteophytes next to notching - Bone formation at the site of triceps release in RTSA (is not the same as notching)”

“Additional bone formation”

“Use standardized X-rays and compare.”



“Usually noted on inferior glenoid in RSA. Presence in anatomic TSR may indicate inadequate surgical technique and lead to implant impingement”

“Size and location”

“Change from one time point to next”

“Most relevant in the setting of a hemiarthroplasty - looking for bony changes on the glenoid side”

“Local growth of reactive bone”

“Findings on radiographs may call for additional CT or MRI.”

“Heterotypic ossification-- degree, progression, time from surgery failure to remove osteophyte-- poor reconstruction”

“Developing bone with time on the glenoid or humerus or as heterotopic ossification in the periarticular soft tissue”

“Bony formation, or heterotopic ossification relates to filling of spaces between the glenoid and the acromion and/or the humerus by aberrant bone tissue as seen in three oriented radiographs. Kjaersgaard-Andersen E Frich LK, Sojbjerg JO, Sneppen O: Heterotopic bone formation following total shoulder arthroplasty. J Arthroplasty 4:99, 1989”

“Boehm, Wallace, Neumann JSES 2005 6-10 Heterotopic ossification after total shoulder arthroplasty Sperling et al J Arthroplasty 2000 179-82”

“Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021. Epub 2008 Sep 5. Radiographic analysis of shoulder anatomical arthroplasty. Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G.”

“Signs of bone-prosthesis impingement”

“Hemis can build osteophytes just like primary arthritis.”

“Bony formation is to be described as traction spurs, reactive bone formation in notching or peri articular calcification.”

“Bony excrescence: defined as a pillar scapular spur if it was absent pre-operatively and if it was in continuity with the bone of the scapular neck post-operatively Ossifications: defined as heterotopic bone in the glenohumeral space if not in continuity with the scapular neck Melis B1, DeFranco M, Lädemann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.”

“Preop x-rays, hemis (glenoid osteophytes/spurs/erosion)”

“On glenoid for reverse”

“Heterotopic bone. Mechanical impingement with spurs / osteophytes - reduced movement and pain.”

“Heterotopic bone. Copy of hip classification.”

“Short description of the extent (mm) and anatomic localization.”

“Very seldom clinically relevant”

#### Bone resorption (e.g. tubercula, tuberosities, cortices)

##### *Summary of most-relevant responses*

- Definition items
  - Difference “bone resorption”(@ tuberosity / stress shielding) vs “osteolysis”(Calcar bone loss) ?
  - Periprosthetic bone loss over time either visible as complete disappearance, partial disappearance or loss of bone mineral density
  - Location: glenoid / area of the calcar / shaft (around proximal metaphysis / greater tuberosity adjacent to humeral head component)
  - Disappearing of bone / bone loss under the implants
  - The location of full cortical bone resorption is assessed by measuring the distance from the base of the stem component to the starting point of bone resorption and categorized according to the zones defined by (Sperling et al 2000)
  - Yes/no question for the greater and lesser tuberosities (partial or complete resorption?), the rest is included in the Sperling Classification
  - Consistency with the zones defines for radiolucencies (e.g. Sperling et al)
- Images: requires CT if seen on X-rays?



- References:
  - Nagels et al , Stress shielding and bone resorption in shoulder arthroplasty 2003 Volume 12, Issue 1, Pages 35-39
  - Sperling et al. Rowland Radiographic assessment of ingrowth total shoulder arthroplasty J Shoulder Elbow Surgery, 9 (2000), pp. 507-513
  - Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G. Radiographic analysis of shoulder anatomical arthroplasty. Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021.

*Original unsorted open-text responses*

“Difficult and of little clinical importance for me. Only for tuberosities in fracture, but also not with high clinical correlation.”

“How does bone resorption differ from osteolysis? Calcar bone loss(osteolysis?) may be different then tuberosity(stress shielding?). Is the amount of bone loss a factor in differentiating SS vs osteolysis?”

“Progression on serial X-rays”

“Any obvious osteopenia”

“Especially in the glenoid aspect”

“Around the shaft”

“Axial CT for definition of thickness of cortex, position and quality of tubercula”

“Use standardized X-rays and compare.”

“Noted around proximal metaphysics adjacent to humeral head component”

“Size and location”

“Change from 1 time point to next, especially over greater tuberosity“

“Site and if progressive / associated with change in prosthesis position”

“Bone resorption can be seen in the glenoid or in the area of the calcar”

“Findings on radiographs may call for additional CT or MRI.”

“Location, progression, timing from surgery”

“A disappearing of bone with further follow up after fracture arthroplasty or bone loss under the implants“

“If asymptomatic patient more an observation”

“Bone resorption - The location of full cortical bone resorption is assessed by measuring the distance from the base of the stem component to the starting point of bone resorption and categorized according to the zones defined by Sperling et al. J.W. Sperling, R.H. Cofield, S.W. O'Driscoll, M.E. Torchia, C.M. Rowland Radiographic assessment of ingrowth total shoulder arthroplasty J Shoulder Elbow Surgery, 9 (2000), pp. 507-513“

“Eur J Radiol. 2008 Oct;68(1):159-69. doi: 10.1016/j.ejrad.2008.07.021. Epub 2008 Sep 5. Radiographic analysis of shoulder anatomical arthroplasty. Merolla G1, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G.”

“Signs that can suggest infection or mechanical problems related to bone healing”

“Resorption around implants is an important aspect to assess.”

“I would only put in a Yes/no question for bone resorption for the greater and lesser tubercle, the rest is included in the Sperling Classification”

“Suspicion of infection”

“Obvious”

“Bone resorption has to be described as in location more likely as in the zones of radiolucency,”

“Partial or complete resorption of the tuberosities: determined by comparing radiographs taken at the most recent follow-up with the immediate post-operative radiographs (difficult and subjective)”

“All implants”

“Periprosthetic bone loss over time either visible as complete disappearance, partial disappearance or loss of bone mineral density”

“This can be seen under the prosthesis in the surface hemiarthroplasties.”

“All of the above”



“Localised area of radiolucency of resorption of cortical bone on radiographs when compared to original radiographs”

“Trauma cases - tuberosities resorption. Instability of implant. Infection. Stress shielding.

“Research into how to make consistent”

“January-February, 2003 Volume 12, Issue 1, Pages 35-39 Stress shielding and bone resorption in shoulder arthroplasty\* Jochem Nagels, MD, Mariëlle Stokdijk, PhD, Piet M. Rozing,”

“Short description of extent (mm) and anatomic zone.”

“Only important in symptomatic fracture patients - sign of rotator cuff insufficiency - difficult to address”

## Stress shielding

### *Summary of most-relevant responses*

- Definition items
  - Bone loss most evident around upper shaft or metaphysis (medial side of the humerus shaft? / medial calcar)), close to the implant
  - Bone resorption on the one side and sclerosis on the other???
  - Bone resorption limited to certain periprosthetic radiographic zones
  - Refers to loss of humeral bone tissue located proximal to the area of prosthesis fixation and describes a progressive loss of trabecula and thinning of cortices secondary to sparing of load from areas nearer to the joint when the implant is fixed, either by cement or by bone ingrowth, to more distal part of the humerus. Stress shielding is therefore an educated interpretation of plane radiographs that acknowledges the role of mechanical forces on bone turnover and remodeling and identifies stress shielding as the cause for bone resorption in this specific scenario (Schmidutz et al 2014)
  - Stress shielding is an interpretation. I would prefer to call it resolution.  
Causes of bone resorption: mechanical factors (stress shielding, instability), conflicts or biological factors (poly wear, infection).
  - Development of medial and lateral cortical bone narrowing associated with osteopenia in zones 2 and 6, condensation lines around the tip of the stem, and a spot weld between the cortical bone and the stem. (Melis et al 2011)
  - Consistency with the zones defines for radiolucencies (e.g. Sperling et al)
- Images: Needs assessment on both AP and lateral views
  - requires CT if seen on Xrays?
- References:
  - Schmidutz et al Stress-shielding induced bone remodeling in cementless shoulder resurfacing arthroplasty: a finite element analysis and in vivo results. J Biomech. 2014 Nov 7;47(14):3509-16. doi: 10.1016/j.jbiomech.2014.08.029.
  - Nagels et al Stress shielding and bone resorption in shoulder arthroplasty JSES 2003 35-39
  - Melis et al An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.

### *Original unsorted open-text responses*

“I think this is a very important and necessary definition.”

“he progression and amount of stress shielding”

“Bone quality”

“To define the implant-loading characteristics”

“Most evident around upper shaft or metaphysis. Needs assessment on both AP and lateral views”

“Size and location”

“Bone loss”

“Site and if progressive / associated with change in prosthesis position”

“Findings on radiographs may call for additional CT or MRI.”



“Association with implant motion, timing from surgery, progression”

“Bone loss on the medial side of the humerus shaft, close to the implant”

“Less important. More an observation. Nothing is done about it.”

“Refers to loss of humeral bone tissue located proximal to the area of prosthesis fixation and describes a progressive loss of trabecula and thinning of cortices secondary to sparing of load from areas nearer to the joint when the implant is fixed, either by cement or by bone ingrowth, to more distal part of the humerus. Stress shielding is therefore an educated interpretation of plane radiographs that acknowledges the role of mechanical forces on bone turnover and remodeling and identifies stress shielding as the cause for bone resorption in this specific scenario. J Biomech. 2014 Nov 7;47(14):3509-16. doi: 10.1016/j.jbiomech.2014.08.029. Epub 2014 Sep 9. Stress-shielding induced bone remodeling in cementless shoulder resurfacing arthroplasty: a finite element analysis and in vivo results. Schmidutz F1, Agarwal Y2, Müller PE3, Gueorguiev B2, Richards RG2, Sprecher CM2.”

“Stress shielding and bone resorption in shoulder arthroplasty Nagels JSES 2003 35-39”

“Sign observed whenever you have distal fixation of the humeral component”

“Stress shielding is an interpretation. I would prefer to call it resorption. Resorption might be due to stress shielding but also to other mechanical factors (instability, conflicts) or to biological factors such as poly wear or infection.”

“Cortical reaction”

“X-rays signs”

“Spot welds, medial bone Resorption, condensation lines”

“This including formation of pedistals can be signs of loosening”

“According to Literature by Nagels et al In stemless prosthesis Bone on growth or bone loss around the SA”

“The presence of stress shielding was defined as the development of medial and lateral cortical bone narrowing associated with osteopenia in zones 2 and 6, condensation lines around the tip of the stem, and a spot weld between the cortical bone and the stem. Melis B1, DeFranco M, Lädemann A, Molé D, Favard L, Nérot C, Maynou C, Walch G. An evaluation of the radiological changes around the Grammont reverse geometry shoulder arthroplasty after eight to 12 years. J Bone Joint Surg Br. 2011 Sep;93(9):1240-6. doi: 10.1302/0301-620X.93B9.25926.”

“All implants”

“Bone resorption limited to certain periprosthetic radiographic zones due to lack of strain in the bone-implant interface.”

“As above”

“On medial calcar”

“See above”

“Localised area of radiolucency of resorption of cortical bone on radiographs when compared to original radiographs J Shoulder Elbow Surg. 2003 Jan-Feb;12(1):35-9. Stress shielding and bone resorption in shoulder arthroplasty. Nagels J1, Stokdijk M, Rozing PM.”

“Research into how to make consistent”

“Short description of extent (mm) and anatomic zone according to Sperling et al.”

“Radiological sign causing bone Resorption on the one side and sclerosis on the other”

“Seldom clinically relevant - visible quite often in the calcar area of the humerus”

### Scapular notching (reverse SA)

#### *Summary of most-relevant responses*

- Definition items
  - Sirveaux classification (grade 3 or more?) / Favard classification
  - Bone resorption of the scapular neck as an effect of bony contact between the humeral component of a reverse prosthesis and the scapular neck. The amount of resorption is graded by the scale of Nérot / Sirveaux
  - Loss of bone tissue from the scapular body immediately adjacent to the glenosphere at the inferior border of the neck of the scapula as seen on radiographs and quantified as described by Sirveaux .
  - Bone resorption in the inferior portion of the neck of the scapula
  - Distinguish between mechanical and biological notching?
  - The definition must include anterior, posterior and inferior notching



- Relevance: We do not act on asymptomatic notching
- Imaging: correct orientation of an AP X-rays is mandatory.
  - Clear axillary view with visualisation of gleaned bone may also show notching anteroinferior or posteroinferior
- References:
  - Sirveaux F. Grammont prosthesis in the treatment of shoulder arthropathies with massive cuff tear. Multicenter series of 42 cases [in French]. Medical doctor thesis, Nancy I University (France), 1997.
  - Sirveaux et al. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. J Bone Joint Surg Br 2004;86:388-95.
  - Sirveaux et al. Les résultats radiographiques. Rev Chir Orthop 2007;93(Suppl 3):71-4 (in French)
  - Sirveaux et al. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive and non-repairable cuff rupture. In: Walch G, Boileau P, Molé D, eds. 2000 shoulder prostheses: two to ten year follow-up. Montpellier: Sauramps Medical, 2001:247-252.
  - Valenti PH, Boutens D, Nerot C: Delta 3 reversed prosthesis for osteoarthritis with massive rotator cuff tear: long term results. In 2000 shoulder prostheses ... two to ten year follow-up. Edited by: Walch G, Boileau P, Molé D. Montpellier, Paris, France: Sauramps Medical; 2001:253-9
  - Nicholson et al. Scapular notching: Recognition and strategies to minimise clinical impact Clin Orthop Rel Res 2011 2521-30
  - Merolla et al. Early clinical and radiological outcomes of reverse shoulder arthroplasty with an eccentric all-polyethylene glenosphere to treat failed hemiarthroplasty and the sequelae of proximal humeral fractures. Int Orthop. 2016.
  - Lévine et al. Scapular notching in reverse shoulder arthroplasty: is it important to avoid it and how? Clin Orthop Relat Res. 2011 Sep;469(9):2512-20. doi: 10.1007/s11999-010-1695-8.

#### *Original unsorted open-text responses*

“According to Sirveaux”

“Progression on serial X-rays”

“The progression and the relation with the position of the implant. Inferior position and eccentric head, should avoid scapular notching”

“Inferior glenoid”

“To define the implant prognosis”

“Sirveaux classification”

“Scapular notching consists of bone resorption of the scapular neck as an effect of bony contact between the humeral component of a reverse prosthesis and the scapular neck. The amount of reposition is graded by the scale of Nerot.”

“Correct orientation of an AP X-ray vies in RSA is mandatory. Clear axillary view with visualisation of gleaned bone may also show notching anteroinferior or posteroinferior”

“Grading by Sirveaux et al”

“Distinguish between mechanical and biological notching.”

“Inferior glenoid Progression and if associated with heterotypic bone”

“In reverse arthroplasty, bone resorption in the inferior portion of the neck of the scapula”

“If symptom, repeated radiograph to detect implant migration or progress of osteolysis Obvious loosening on radiographs is essential findings.”

“Degree, progression, association with implant motion”

“A stepwise bone loss on the inferior glenoid neck”

“We document it, but no action is taken. We do not act on asymptomatic notching.”

“Loss of bone tissue from the scapular body immediately adjacent to the glenosphere at the inferior border of the neck of the scapula as seen on radiographs and quantified as described by Sirveaux. Sirveaux F, Favard L, Oudet D, Huquet D, Walch G, Mole D. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. J Bone Joint Surg Br 2004;86:388-95.”



“Scapular notching: Recognition and strategies to minimise clinical impact Nicholson Clin Orthop Rel Res 2011 2521-30”

“Int Orthop. 2016 Apr 25. [Epub ahead of print] Early clinical and radiological outcomes of reverse shoulder arthroplasty with an eccentric all-polyethylene glenosphere to treat failed hemiarthroplasty and the sequelae of proximal humeral fractures. Merolla G1,2, Tartarone A3, Sperling JW4, Paladini P3, Fabbri E5, Porcellini G3.”

“Important parameter related to impingement between humeral polyethylene and inferior glenoid neck, that happens when you have a medial centre of rotation in the implant design”

“The definition must include anterior, posterior and inferior notching”

“True AP radiograph of scapula required”

“Sirveaux F. Grammont prosthesis in the treatment of shoulder arthropathies with massive cuff tear. Multicenter series of 42 cases [in French]. Medical doctor thesis, Nancy I University (France), 1997.”

“Grade 3 or more”

“X-rays signs and Favard classification”

“Favard classification”

“Is well described in grades to watch extend there is bone wear at the scapula, at or beyond the inferior screws, central peg”

“According to Sirveaux”

“According to the Sirveaux-Nerot four- grade classification Sirveaux F, Navez G, Roche O, Garaud P, Molé D. Les résultats radiographiques. Rev Chir Orthop 2007;93(Suppl 3):71-4 (in French) and Sirveaux F, Favard L, Oudet D, Huguet D, Lautman S. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive and non-repairable cuff rupture. In: Walch G, Boileau P, Molé D, eds. 2000 shoulder prostheses: two to ten year follow-up. Montpellier: Sauramps Medical, 2001:247-252.”

“Any form of contact of the humeral component with the glenoid bone.”

“This needs to be looked for on the lateral border of the scapula. Also whether it has hit the lowest screws.”

“As usually done”

“References for notching: Valenti PH, Boutens D, Nerot C: Delta 3 reversed prosthesis for osteoarthritis with massive rotator cuff tear: long term results. In 2000 shoulder prostheses ... two to ten year follow-up. Edited by: Walch G, Boileau P, Molé D. Montpellier, Paris, France: Sauramps Medical; 2001:253-9”

“see above”

“Resorption of the bone in notch of scapula at inferior aspect of glenoid owing to humeral component in comparison to original radiograph”

“Progression of notching. Stability of RSA. Implant position.”

“As per current”

“Clin Orthop Relat Res. 2011 Sep;469(9):2512-20. doi: 10.1007/s11999-010-1695-8. Scapular notching in reverse shoulder arthroplasty: is it important to avoid it and how? Lévine C1, Garret J, Boileau P, Alami G, Favard L, Walch G”

“Description according to the Classification of Sirveaux et al.”

“Seldom clinically relevant”

## Implant wear

### *Summary of most-relevant responses*

- Definition items
  - indirectly on xray or CT in reduction of joint space ... use “joint line asymmetry” instead of “implant wear”..
  - mostly seen only at glenoid side and especially PE wear, visualization is described in consecutive X rays as narrowing of joint line
  - progressive narrowing of joint space / change in distance (between the implants)
  - Narrowing / subluxation of the articular surface
  - Can either be concentric or eccentric
  - Important to detect metal-metal contact



- Attritional loss of implant material over time of usage due to abrasion, mostly affecting the contact zones between two articulating components.
- Implant wear is generally difficult to monitor, commonly acknowledged indirectly following imaging findings of bone resorption resulting from monocyte activation by ingestion of plastic particles. Catastrophic implant wear is demonstrated by (uneven) decrease in the space between metal components of the implant (RSA) or the distance between metal to bone (TSA).
- Cause in definitions? mechanical load of the prosthesis
- Imaging: Correctly aligned AP view of glenoid poly essential !
- References:
  - Day et al Polyethylene wear in retrieved reverse total shoulder components JSES 2012 667-674
  - Nam et al Reverse total shoulder arthroplasty: current concepts, results, and component wear analysis J Bone Joint Surg ..., 2010.

*Original unsorted open-text responses*

“Extremely difficult to impossible, only in metal back anatomic glenoids”

“Progression on serial X-rays”

“Any soft tissue metallosis”

“Position of the wear, the progression and relation with osteolysis”

“Distance between the implants”

“Mayo”

“Using standardized X-rays thinning of polyethylene can be measured.”

“Correctly aligned AP view of gleaned poly essential to correctly assess this.”

“Narrowing of joint space”

“Change in distance”

“Narrowing / subluxation of the articular surface Association with lysis / aseptic loosening”

“In total arthroplasty, polyethylene consumption, exceptionally also metal consumption”

“If symptom, repeated radiograph to detect implant wear or progress of wear. Obvious wear on radiographs is essential findings.”

“Decrease in poly thickness, timing from surgery”

“If asymptomatic patient nothing is done. Important to detect metal-metal contact”

“Refers to loss of implant material over time of usage due to abrasion. Implant wear is generally difficult to monitor, commonly acknowledged indirectly following imaging findings of bone resorption resulting from monocyte activation by ingestion of plastic particles. Catastrophic implant wear is demonstrated by (uneven) decrease in the space between metal components of the implant (RSA) or the distance between metal to bone (TSA).”

“Polyethylene wear in retrieved reverse total shoulder components Day et al JSES 2012 667-674”

“Sign of mechanical load of the prosthesis”

“Poly wear is important. Consider asymmetric wear like a a secondary B2 Poly.”

“Difficult to detect, suspicion of PE wear is given in case of progressive joint space narrowing”

“Asymmetric loss of polyethylene or lysis / loosening”

“X-rays signs”

“Difficult to standardize”

“Is harder to describe, wear of implant is mostly seen only at glenoid side and especially PE wear, visualization is described in consecutive X rays as narrowing of joint line”

“A narrowing of the joint line (between glenoid and humeral components) is considered wear”

“Any attritional loss of implant material over time. Mostly affecting the contact zones between two articulating components. Can either be concentric or eccentric”

“Wear can be loosening of usually the glenoid. It can be erosion medially of the glenoid in a hemiarthroplasty”

“Difficult. assessment of space”



“Debris from implant or bearing surface leading to decrease in height / depth on radiograph when compared to immediate postoperative radiograph.”

Subluxation. Thinning of poly.”

“Reverse total shoulder arthroplasty: current concepts, results, and component wear analysis D Nam, CK Kepler, AS Neviaser, KJ Jones... - J Bone Joint Surg ..., 2010 - jbjs.org”

“Radiological sign showing thinning of Joint space (often not symmetrically)”

“Seldom clinically relevant by itself”

### Arthritis (bone, cartilage)

#### *Original open-text responses*

“Only for hemiprostheses, very difficult to quantify, we tried hard and failed to find a quantitative way. Very difficult. would only use a no, moderate, severe score. See also Herschel R, Wieser K, Morrey ME, Ramos CH, Gerber C, Meyer DC. J Shoulder Elbow Surg. 2016 Aug 18”

“Associated with bone loss”

“Very important in case of hemi arthroplasty”

“Mayo and Walch”

“Wear patterns on glenoid in hemiarthroplasty with and change in centre of rotation of the humeral head”

“Secondary bone deformation loss of joint space size and location of osteophytes”

“Progression of disease / bone erosion - particularly in hemiarthroplasty / partial joint replacements”

“If symptom, repeated radiograph to detect gleamed wear or progress of wear. Obvious wear on radiographs is essential findings.”

“I assumed this was a preop radiographic parameter-- loss of joint space, congruity, degree and location of osteophyte production, amount of bone erosion”

“Loss of cartilage seen as minimizing joint space in hemiarthroplasty”

“In hemiarthroplasty glenoid wear may explain pain so it is important to detect, but only in symptomatic patients.”

“Related to partial arthroplasties”

“In HSA, glenoid, according to Walch classification.”

“Mainly in hemi and surface replacement concerning bone loss and extent of migration”

“Arthritis is described as progressive wear in semi arthroplasty. In these cases medialisation of the humeral head can be described with bony references as the base of coracoid and spinoglenoidal notch”

“In hemiarthroplasty loss of joint space”

“Any joint space narrowing after hemiarthroplasty is a sign for secondary glenoid sided osteoarthritis.”

“Loss of joint space, osteophytes, subchondral cyst and sclerosis”

“Only important in symptomatic hemiarthroplasty patients - conversion to total may be evaluated”

### Other parameters

#### *Summary of most-relevant responses*

- Specially for RSA
  - Stress reactions on the acromion: angulation, primary thickness
- Related to additional treatments
  - Migration of the tuberosities for two situations:
    - 1. Refixation to prosthesis in fractures
    - 2. Refixation after osteotomy of lesser tuberosity with subscapularis tendon (on axillary views ... see papers by L Higgins?).
- Events caused in surgery, but not recognised for 24 hrs - i.e. on initial post-operative imaging - this may happen from recovery to the ward e.g. humeral shaft fracture, dislocation.
- Imaging parameters (symptomatic patients)



- For example they want the rotator cuff status, but this requires CT, MRI or US based on a suspicion ... is that possible with SA? Comment: We have to develop a clinically-convenient methodology of assessing cuff functional competence
- Scintigraphy and blood samples in patients with pain □ for possible infection?

Proposed additional parameter	Proposed definition
<ul style="list-style-type: none"> <li>• Scapula / Acromion</li> <li>• Stress reactions (acromion in RSA)</li> <li>• (Stress) fractures</li> <li>• Acromial fracture or fragmentation</li> <li>• Status of rotator cuff</li> <li>• Implant failure - e.g. breakage</li> <li>• Implant breakage, implant dissociation, Fractures/healing (acromion, scapula, humerus, unhealed osteotomy, or tubercle migration, Glenoid wear</li> <li>• Implant failure (Breakage), periprosthetic fracture</li> </ul>	<p>Angulation of the acromion, primary thickness of the acromion</p> <p>Stress fractures of the acromion can be seen in reverse prosthesis . description should be based on fracture location and dislocation</p> <p>Rupture yes and when yes location</p> <p>Breakage - stem, screws, prosthesis itself - including new materials and bearing surfaces- e.g. Pyrocarbon Also dissociation / uncoupling of modular implants</p> <p>If symptom, Implant failure is essential findings. Repeated radiograph to detect fractures and healing disturbance. Glenoid implant wear or progress of wear. Obvious findings on radiographs is essential findings.</p>

*Overall comments / suggestions on imaging parameters*

“I suggest migration of the tuberosities for two situations: 1. Refixation to prosthesis in fractures 2. Refixation after osteotomy of lesser tuberosity with subscapularis tendon Further fracture of the acromion is missing for RTSA”

“Sorry to have more questions than answers.”

“A literature search can give more information than I can reproduce. Compare items with hip and knee classifications and definitions.”

“Modular implant failure needs clear focus / definition - not well covered in current literature - is an uncommon but important cause of catastrophic failure”

“On a side note, it is important to make sure that there is not failure of the lesser tuberosity if an osteotomy was performed. I have seen this before and it is a very subtle finding on axillary views. Dr. L Higgins has two papers on this topic.”

“If followed by plain radiographs for symptoms any findings will be substantial enough to motivate further examination by repeated radiographs or CT / MRI.”

“For us routine radiographic follow up in asymptomatic patients not indicated unless research. Therefore the radiographic Changes are important when the patient has symptoms. Then symptoms are correlated to radiographic findings”

“I have a strange feeling filling in this form. I do not think that a productive consensus is reachable without discussion in a group. My suggestion: Build a core group that comes up with definitions and ask a wider group to comment on the proposed definitions...”

“If the X-ray image is not clear a CT is always done with implant subtraction to evaluate osseous deficiencies”

“I would add implant failure (breakage, dissociation etc) to the list”

“Cases need monitoring but who pays for it ?”

“The radiographic parameters are important in assessing symptomatic patients only the previously described classification systems e.g. zones of radiographic loosening are clinically non-applicable fractures are not addressed by this questionnaire “

“Implant fracture and implant dissociation from itself (modular implants)”



### Imaging parameter monitoring to complication

When do you think factors documented by imaging parameters (as defined previously) lead to untoward events / complications?

#### *Summary of most-relevant responses*

- Mostly misunderstood question: post-OP ...
- When identified
- When a surgical intervention done
- When seen early post-OP (within 3 months)
- When progression (above some predefined level of severity?)
- When poor clinical results (AULA: so symptomatic?)
- Lack of understanding of the question: e.g. "Post-operative"
- Most relevant comment: When associated with symptoms / deterioration of clinical performance  
 "I think asymptomatic changes on X-ray will rarely require intervention, but deterioration of clinical performance accompanied by radiological changes is a complication that indicate need for intervention."

#### *Initial unsorted responses*

"Mostly postoperative"

"Any of the factors documented by imaging parameters which would lead to a surgical intervention after the initial operation should be considered a complication."

"Fracture of the shaft dislocation of the tuberosities loosening of shaft or glenoid in anatomical or RTSA Acromion fracture malpositioning (maltorsion mainly), over or understuffing poor cementation technique posterior dislocation"

"Malalignment and vault perforation"

"Early postop within three months or after 3 to 5 years"

"Excepting malalignment on post-operative film, all other radiological 'problems' are post-operative"

"When there are progression of the parameters and /or there are a poor clinical result"

"During the first six months, which is why I like to see an X-ray (screening) at 3/12 (and, if necessary at 6/12 if symptoms persist or evolve)"

"Varies"

"This is depending of the type of complication. A dislocated insert leads to an immediate event and reoperation. A not well implanted prosthesis can eventually cause a reoperation in the future (e.g notching in a case of a to high implanted head on the glenoid). This might not harm an older patient at all, in the case that the patient hasn't a long life expectancy."

"Usually postoperatively unless technical malposition of components is noted"

"??"

"I'm not sure I understand your question. We routinely perform postoperative X-ray to document the positioning of implants and status of bone quality. At this point it is also possible to identify fracture lines if overlooked during surgery, dislocation of implants. Radiolucent lines along the glenoid implant is total SA are to be observed longitudinally as these rarely are accompanied by reduced clinical performance. Migration of the humeral head e.g. may indicate a cuff deficiency e.g. a tear and is more often accompanied by reduced clinical performance. I think asymptomatic changes on X-ray will rarely require intervention, but deterioration of clinical performance accompanied by radiological changes is a complication that indicate need for intervention."

"The question is not clear to me"

"Variable"

"As soon as they may be observed"

"Should also include events caused in surgery, but not recognised for 24 hrs - i.e. on initial post-operative imaging - this may happen from recovery to the ward eg humeral shaft fracture, dislocation"

"Postoperative (e.g. early instability) or at follow-up"



“Uncertain as to the meaning of this question. Are the imaging parameters over read, causing a surgeon to think a complication may be present when it is actually not?”

“Migration or loosening that progress Implant breakage or wear”

“When the severity of deformity is under appreciated by the surgeon.”

“When RLL are complete around the implant and >0.5mm are defined as loosening and complication. If instability leads to subluxation if notching touches the screws any kind of implant migration bone loss with implant loosening”

“Sometimes a malpositioning of the implant may lead to dislocation, early loosening”

“Question not clear”

“PE wear in metal to metal components- metallosis and lossening scapular notching – loosening”

“As soon as recognised”

“In combination with symptoms of the patient”

“Whenever they are related to clinical complaint”

“I am not smart enough to understand this question. I would be better to ask: Do you think that primary radiolucent lines between cement and scapular bone represent a bad prognostic factor? and so on...”

“I don’t know! “

“When they progress, not necessarily a particular timepoint or severity”

“Fractures and/or instability could happen within the first minute of leaving the OR...  
 implant loosening”

“I don't get the question”

“? Zu jedem Zeitpunkt kann eine Bilddokumentation eine Komplikation abbilden“

“D0”

“Within the first year”

“Many different factors (may lead to complications / untoward events at different points of time)”

“Progression of loosening or evidence of dislocation or subluxation”

“Postoperative”

“Unless there is a fracture, then the previous documented events are all late onset years after the event”

“Between incision and post op X-ray”

“Implant Migration /loosening will be detected earliest at 6-9 months, latest at 10-15 years  
 postoperatively“

“This can be early, progressive with time or late. May be progressive with time. For example: Early = poor position of implants, may lead to early wear, dislocation, cuff failure. Progressive = loosening, osteolysis Late = wear, cuff failure.”

“Implant Migration and signs of shoulder instability could be visible in the Primary postoperative period as well. Whereas all bone related changes are visible after a minimum of 6 months period.”

“Dislocation can happen immediately postoperative, therefore X-ray before patient is discharged from Hospital, next X-ray not before 3 months”

“I think all adverse events/complications are primarily clinical and only thereafter their nature can be further investigated by e.g. imaging. However, during the early postoperative painful period radiographic imaging must be obtained to document the positioning and integrity of the construct.“

“Starting at least in the recovery room.”



## File 7: SA Radiological Monitoring v1.0 - Delphi 02 survey results – March 2018

### SA Radiological Monitoring v1.0

### Core list of radiological parameters for shoulder arthroplasty (SA) monitoring

### Delphi 02 survey results

### March 2018

From 181 invited experts, 68 (38%) participated and 65 completed the survey.

The experience of participants in orthopaedics and SA can be summarized as follows:

Annual number of ARCR**	Years of experience*				Total
	1-5	>5-10	>10-20	>20	
1-20	-	4	2	1	7
>20-50	1	7	8	9	25
>50-100	-	2	11	10	23
>100	-	1	5	7	13
Total	1	14	26	27	68

\* How many years of surgical experience do you have in orthopaedics?

\*\* On average, how many shoulder arthroplasties do you perform annually?

#### General comments

"good exercise"

"Great to participate"

"Very good review of all parameters to be considered after prosthesis implant"

"It would be useful to have a means of scoring how 'good' the shoulder replacement is or to put it another way how well has the prosthesis been positioned. This would be useful to audit how well we are doing and if we are scoring better with time as we progress. In hips there are measures such as maintaining correct leg length, offset, cup position, alignment and cement integration etc. In shoulders it would be useful to have a measure of eg 'over stuffing', head prominence above tuberosity etc."

"thanks for including me in participation!"

"Good work. Keep going ;-)"

"We do not know what the lifespan is of a shoulder prosthesis. We also don't have proven good implants yet. It is advisable to survey shoulder prosthesis to be kept informed about adverse events. This can be done 2 or 3 yearly. Hemiprosthesis are mainly used in younger patients. What we don't want is an eroded glenoid in which a bone graft is needed for the revision. In these cases a reverse with bonegrafting is needed then. That should be avoided as long as possible in these young patients. Therefore in hemi's monitoring is essential to be able to convert to a total anatomical on time before the only solution is a reverse."

"Not at the moment good job!"

"Consensus is a great aim, but difficult to reach without physical interaction. In fact reaching consensus cannot be based on a voting process. It requires the group to hear the various arguments, understand them and to feel the common intelligence shifting in a given direction. It is comparable to a flock of birds flying wildly in formation."

"Great process but the rapidly expanding types of joints in both reverse morphology and materials science will mean regular revision of this."



"Nice work!"

"Great Job!"

"Thank you very much for the opportunity to participate and contribute to this important and valuable project. Best wishes for the future and success of this project. "

"Great work guys!"

"Tremendous work. Thank you for the opportunity to participate. "

"Very interesting project"

"The repeatability of the images and compared to previous radiographic features over time has in my experience been difficult. Although comparing first postoperative X-ray to the most recent radiograph especially if several years later is often helpful in assessing if obvious changes have occurred. Therefore minimum requirements will limit the ability to assess features such as wear or loosening."

"Great job you are doing"

## Implant migration (e.g. subsidence, tilt, shift)

Based on a proposal by Dr. Bjorn Salomonsson (Karolinska Institutet Danderyds Sjukhus AB, Stockholm, Sweden)

**Definition of terms :** Implant migration is a noticeable change of the position of the implant, relative to the bone it is supposedly fixed to (either cemented or uncemented).

**Specifications :**

**Subsidence :** migration in a specific direction. Subsidence of a humeral implant is measured relative to the highest point of the greater tubercle (but not if it is the tubercle that migrates), and a medial migration of the glenoid component relative to the base of the coracoid on AP radiographs of the shoulder. A migration should be >1 mm to be considered true in an individual case.

- **Tilt :** migration as a rotation of the implant. Tilt of the humeral component is measured relative to the mid-shaft line of the humerus. Tilt of the glenoid component is measured relative to the plane of the under-surface of the acromion. A tilt of >5° is considered true if the radiographs are taken in the same plane.

- **Shift :** migration as a combination of direction and rotation.

*Brinke B.T., Beumer A., Koenraadt K.L.M., Eygendaal D., Kraan G.A., Mathijssen N.M.C. The accuracy and precision of radiostereometric analysis in upper limb arthroplasty, Acta Orthopaedica 2017, 88(3):320-325*

*Streit J.J., Shishani Y., Greene M.E., Nebergall A.K., Wanner J.P., Bragdon C.R., Malchau H., Gobeze R. Radiostereometric and radiographic analysis of glenoid component motion after total shoulder arthroplasty, Orthopedics 2015, 38(10):e891-e897*

*Valstar E.R., Gill R., Ryd L., Flivik G., Börlin N., Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants, Acta Orthopaedica 2005, 76(4):563-572*

### Notes

- We accept that in some situations, the defined reference points (greater tuberosity or acromion) may not be adequate for the measurement of the respective migration parameters.

- Severity level indicating the radiographic observation as an untoward event: Implant migration is of interest in the evaluation after shoulder arthroplasty, mainly as an indication of possible loosening or malposition that is to be regarded as a complication after the joint replacement. However, implant migration without any clinical symptoms or deterioration of function is not specifically defined as a complication, but may indicate a need of future monitoring of the implant. Infection and loosening may be events associated with implant migration, but these causes should be considered higher in the hierarchy of complications compared to migration.

- A suspicion of subsidence, tilt or shift may lead to further diagnostic by CT scans.

- Implant migration may have different patterns. Early migration during settling in the first months, followed by a stable situation is normal for some types of implants, especially uncemented implants are reported to settle before fixation. Contrary a continuous migration without stabilization is considered to be a not fixed implant. Initial stability



followed by later migration should be considered as a sign of loosening of the implant. However, also a loose implant may be without migration on subsequent radiographs.

- Implant migration do not include complications related to failure of the implant by breakage, dissociation, disassembly or articular dislocation. Also cement fractures or cement migration is not included in implant migration, but could be indications of loosening.
- Implant migration do not include translation relative to other bony structures than the one where the implant is supposed to be fixed, e.g. a humeral implant is not considered to be migrated relative to the glenoid (glenoid erosion or wear) or acromion (cuff deficiency). Neither is a migration of tubercles (e.g. after a fracture arthroplasty) defined as an implant migration.
- Implant migration do not include change of the bony structure by stress shielding, osteolysis or radiolucent lines, without any change of the absolute position of the implant in relation to the main bone structure.
- For research the RSA method is the gold standard to measure implant migration, but this is usually not feasible for clinical routine monitoring. For clinical monitoring of implant migration plain radiographs in neutral position of rotation in AP view is the most informative examination.
- Implant migration is a change of position (of the implant) that occurs over a period of time between subsequent radiographic examinations. It is not a malposition noted direct postoperatively. If motion of the implant is noted during an examination, as during provocation, then the implant instead is to be considered to be loose.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	1 (1)
	Yes	66 (99)

#### *Comments or alternative suggestions*

"Measuring gleaned migration relative to the base of the coracoid is inherently inaccurate. This is mainly because it is very difficult to get standardised radiographs. I agree this is the best option when using X-rays but a CT would be more accurate."

"Using absolute measurement limits is problematic. You could argue that any change in prosthetic seating even below these limits is subsidence or tilt. However, in clinics it is not possible to detect a 1mm or 5 degree change as radiographic projections may differ considerably. Instead of using absolute measurement one could say that any change in prosthetics height is subsidence, but for the clinical definition to term this as no/potential/marked."

"Radiographs for evaluation have to be taken in comparable planes, safety corridors of plane deviation should be defined. "

"Tilt should also be defined for stemless humeral components "

"A migration of > 1 mm or a tilt of > 5 gr. are considered 'true' for the defined parameters. These thresholds seem very optimistic in terms of measurement variability and clinical relevance."

"the measurement relative to coracoid can be very variable and 1 mm seems very strict."

"subsidence = migration of the implant along its main axis compared to the immediate post implantation position.  
tilt = migration of the implant resulting in an angulation of its main axis compared to the immediate post implantation position. (Rotation is misleading- what about rotation around the axis of the shaft?) shift  
(Translation)= migration of the implant in a sideward direction compared to the immediate post implantation position  
"

"Migration can also occur after autograft and allografting of the glenoid and again may or may not be clinically or radiologically significant"



## Radiolucency around the implant / Implant loosening

Based on a proposal by Dr. John Sperling (Mayo Clinic, Rochester, Minnesota, USA) and Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

### Definition of terms :

Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant, bone-cement or cement-implant interface.

Implant loosening is considered when respective components are identified with Grade 4 lucency (see below) or a shift in position (see previous section) between postoperative radiographs (implants at risk of failure based on radiographic outcome).

### Specifications :

RLL are documented according to their presence or absence, location and thickness, separately for the humeral and glenoid components. The humeral component is further divided into metaphysis and diaphysis according to the surgical neck of the humerus (visible on standard radiographs).

Within each of these locations (as appropriate for various prosthesis types), the severity of RLL occurrence is graded as follows:

Grade 0 : None (any RLL are < 0.5mm in width)

Grade 1 : Incomplete RLL < 1.5mm in width

Grade 2 : Incomplete RLL reaching 1.5mm in width

Grade 3 : Complete with some RLL < 1.5mm in width

Grade 4 : Complete with all RLL reaching 1.5 mm in width (loosening)

*Sperling J.W., Cofield R.H., O'Driscoll S.W., Torchia M.E., Rowland C.M. Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg 2000, 9(6): 507-513*

*Schoch B.S., Barlow J.D., Schleck C., Cofield R.H., Sperling J.W. Shoulder arthroplasty for post-traumatic osteonecrosis of the humeral head. J Shoulder Elbow Surg 2016, 25(3):406-412*

### Notes

- Severity level indicating the radiographic observation as an untoward event: development of symptoms, implant loosening (Grade 4 lucency) and/or revision of arthroplasty.

- Loosening could be aseptic or due to infection. In the latter case, infection is the leading adverse event.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	3 (4)
	Yes	64 (96)

### Comments or alternative suggestions

"Please clarify the difference between complete and incomplete"

"0 ok 1 ok 2 incomplete RLL equal or >1.5mm 3 complete with all RLL <1.5mm 4 complete with some RLL = or > 1.5mm I did not find the other grades as easy to understand"

"pls see the previous, I would not use absolute measurements. "

"Basically, I agree. However, a measurement size of 1.5 mm is very prone to measurement errors. "

"Again, comparable radiographic planes are important."

"Suggest just amend Gr I - to 0.5-1.5mm to fit the definitions between Gr 0 and Gr 2"



"Incomplete and complete must be defined more clearly in this Setting. Is the RL incomplete or is the RL just in parts of the Prostheses and if so where?"

"I doubt whether measurements within a range of 0.5mm are possible based on standard radiographic images in a clinical setting."

"Please make sure that it is clear that this is a classification based on conventional X-rays and therefore largely approximate."

## Signs of shoulder instability

Based on a proposal by Dr. Philipp Moroder (Charité Universitätsmedizin Berlin, Germany)

Definition of terms : Shoulder instability refers to a loss of alignment of the articulating surface of the humeral component with the articulating surface of its joint partner.

Specifications :

- Static instability: non-arm position-dependent eccentric misalignment with residual contact visible on standard radiographs.

- Dislocation: non-arm position-dependent complete loss of contact visible on standard radiographs.

Notes

- Dynamic instability (arm position-dependent loss of contact) requires functional radiographs (horizontal flexion/extension view in 90° of abduction or otherwise, if that cannot be achieved by the patient, internal and external rotation AP view in 0° of abduction, as well as true AP view in 60° of abduction) and therefore, cannot be documented in routine monitoring of asymptomatic patients using standard radiographs. Functional imaging is recommended only in the case of clinically suspected dynamic instability (i.e. in the presence of symptoms). This event is therefore addressed in the Core Event Set.

- Severity level indicating the radiographic observation as an untoward event: A dislocation is considered an adverse event/complication regardless of symptoms or required revision surgery. Static and dynamic instability are only considered as adverse events/complications in the presence of symptoms or required revision surgery due to eccentric component wear or bone loss.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	6 (9)
	Yes	61 (91)

## Comments or alternative suggestions

"especially in anatomic TA it is a very subtle process to come to the diagnosis of an instability which is not leading to complete dislocation as the relative exposition of the implants depends greatly on the position and also the muscle activity when taking the radiographs"

"A degree of instability/subluxation may be physiological/normal Grey area defining pathological instability. Would a numeric measure of subluxation be useful looking at % displacement from perfectly superimposed centres of rotation of ball in socket being not 'unstable'. and movement of centre of head moving more than 1 radius from centre up socket being complete displacement/dislocation"

"Instability is a dynamic phenomenon, associated with symptoms Suggest Instability = symptomatic loss of alignment of articulating surfaces triggered by movements Static subluxation & dislocation = persistent loss of alignment that may be symptomatic or asymptomatic It is the symptomatic ones that indicate need for further intervention"

"Most patients with instability will display them on x-ray, but to me it is not required for the diagnosis since it can be assessed clinically (in cases of 'dynamic' instability)"



"I consider axillary view as a dynamic functional radiograph helping to detect anterior instability (static as well as dynamic) in case of subscapularis deficiency. If superior or postero-superior cuff insufficiency is suspected we should try to agree on the best imaging study to confirm it, since MRI is limited and CT sometimes does not really help. Can we agree on a set of functional x-ray to confirm cuff failure. I don't mean ap-view when superior migration is already obvious."

"It should be made clear that this is for static instability only"

"In case of radiographically invisible PE-inlays, assessment of the degree of articulation might be difficult, is there a point-to-point contact or not?"

"if the malalignment is in a certain direction, do we need to define the glenoid as the referent aspect of the articulation for the sake of clarity? so the humeral head is anterior to the glenoid etc? and be described in terms of location on both AP and Lateral radiographs?"

"Agree with definition, though it may be worthwhile to emphasize instability visualized on axillary radiograph from superior migration from cuff insufficiency. "

"the diagnosis of dynamic instability can also be made by the difference of the prosthesis Position in the Standing and the supine Position (for example between conventional radiographs and the MRI)"

"the time factor is important here, subluxation of the prosthesis is not necessarily pathological at early 6 weeks consultation"

"Instability is a dynamic, not a static concept. If an implant is not well aligned on a given X-Ray I will call it dislocated or sublimed. Even better are these terms for instance: posterior gleno-humeral translation 5mm, posterior scapula-humeral translation 8mm. Or superior gleno-humeral translation whit reduction of the acromio-humeral distance to 2mm....."

"The direction of instability should be added. A differentiation between anatomical and reverse designs should be added."

## Bone resorption / Bone formation / Osteolysis

Based on a proposal by Dr. Simon Lambert (University College London Hospital, London, UK)

### Definitions :

Bone resorption: the progressive disappearance of bone from the humerus and/or scapula following SA when compared to the preoperative condition.

Bone formation: the progressive apposition of bone on or in the humerus and/or scapula following SA when compared to the preoperative condition, more than that required for stable integration of the prosthesis.

- Homotopic bone formation (homotopic ossification) is bone formation within the confines of the bone including the periosteum: bone is formed within tissue that is destined to be or become bone under normal healing or loading conditions.

- Heterotopic bone formation (heterotopic ossification) is a subset of excess bone formation within or between tissues that is not destined to be or become bone under normal healing or loading conditions.

### Specifications :

Bone region-based description of periprosthetic occurrence / extent of bone resorption / formation:

- Humeral side: further divided into metaphysis and diaphysis according to the surgical neck of the humerus (visible on standard radiographs).

- Glenoid side (without further division)

Heterotopic bone formation is classified according to the Brooker classification\*\*

*\*\*Brooker AF, Bowerman JW, Robinson RA, Riley Jr LH. Ectopic ossification following total hip replacement: incidence and a method of classification. JBJS 1973;55:1629-1632.*

### Notes

- The terms osteopenia (diminished bone quality or density) and osteolysis (absent bone) may be considered synonyms that should be avoided, since they imply an observation at a specific point in time rather than a progressive disease. The term osteolysis is often used in association with more actively destructive bone loss such as that seen in



oncological disease or fulminant infection, where the disequilibrium between bone destruction and bone formation favours the former. It is a subset of bone resorption. However, the term osteolysis is often used indiscriminately and does not always imply active destruction. In this sense, the term is unhelpful. We suggest that bone resorption is the more useful term, since it actually describes what is seen on imaging and in histology but does not imply or define a specific disease process.

- Radiographic features show absence or hypo-density of bone previously present or of normal quality (manifest as "lucent lines", loss of bone structure or density, loss of bone mass), yet detection in a series of radiographs is poorly reliable. Radiographic screening in asymptomatic patients can raise suspicions of bone resorption; CT imaging should be used to confirm bone resorption status in symptomatic patients.

- Severity level indicating the radiographic observation as an untoward event: In the presence of symptoms or required revision surgery due to associated implant loosening.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	2 (3)
	Yes	64 (97)

#### *Comments or alternative suggestions*

"The site of any bone Resorption can be crucial when it occurs in a region where tendons or muscles insert (e.g. tuberosities , deltoid Insertion,...) in other cases can be due to stress shielding and of minor importance"

"I would not rely on using CT to confirm or detect bone resorption, because you might not have a post-operative CT scan. So a not perfectly seated implant (not flush with the bone) could also make the impression of bone resorption."

"I think the definition for bone resorption should be '...when compared to the condition at day 1 after surgery'. Anything can happen during surgery. But maybe that complicates the terminology in total? I agree with the other definitions specifications and terminologies."

"Again, comparable planes of radiographs appear essential."

"The definition of homotopic bone formation is seldom if ever clinically significant"

"should the resorption or formation be described in terms of location on both AP and Lateral radiographs? and use conventions to describe location with respect to glenoid and humeral components? Should long held classifications such as Sirveaux for glenoid notching be utilized?"

"The term 'progressive' in the definition calls for some additional information about the number of images and the time between them to detect a 'progression'."

"I think it is difficult to make a difference between bone Resorption and osteolysis ,1 is Greek, the other English"

"not agreed with 'preoperative' condition. It should be 'directly postoperative' postoperative condition within 1 week postoperatively. This is due to the fact that during SA, bone is resected and thus this should be the baseline and not the preoperative radiograph"

"All bony changes should be compared to the immediate post implantation condition, not to the preoperative condition. Orthotopic bone is used 20 times more frequently than homotopic bone - google search! "

"Radiographic changes at the calcar regions should be added. These changes (i.e. medial calcar resorption or bony ongrowth) are not directly related to the implant but an important observation in particular with stemless designs."



## Scapular notching (specific to reverse SA)

Definition of terms : Scapular bone resorption with disruption of the normal contour (= notch) near the glenoid base plate.

Causative factors :

- a) contact/impingement of the cup of the humeral component and the inferior bone of the scapula.
- b) polyethylene wear particles triggering osteolysis.

Specifications : Classification of the extent of glenoid erosion according to the Sirveaux classification\*.

Grade 1 = notch limited to the scapular pillar

Grade 2 = notch reaching the inferior screw of the base plate

Grade 3 = notch extending beyond the inferior screw

Grade 4 = notch reaching the base plate central peg.

\* Sirveaux F., Favard L., Oudet D., Huquet D., Walch G., Mole D. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. Results of a multicentre study of 80 shoulders. *J Bone Joint Surg Br* 2004; 86(3): 388-95.

### Notes

- Although it is considered a form of bone resorption, scapular notching is a separate entity due to its direct association with reverse SA.
- The Sirveaux classification system has some limitations due to the variety of prosthesis designs and its dependency on the placement of the inferior screw of the base plate, yet we are not aware of a better alternative for documentation. This system currently remains widely accepted and used.
- Severity level indicating the radiographic observation as an untoward event: When the progression of notching is associated with implant breakage (e.g. screw), or symptomatic implant loosening or migration, or implant revision.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	4 (6)
	Yes	60 (94)

### Comments or alternative suggestions

"If it relates to erosion relative to distal screw then shoulders could be designed without an inferior screw, or one may not be put in. Should be a percentage loss of glenoid height"

"Notching does not always occur inferior but rather postero-inferior or antero-inferior. We should find a way to detect the real location of notching to help prevent it by placing the components differently, using smaller or bigger implants or using different angles of inclination of the humeral component."

"I would recommend using bone resorption. This same phenomenon is visible in anatomical TSA on the humeral calcar region due to contact with the glenoid poly - and not called notching."

"Many models do not use a truly 'inferior' screw anymore, so there is a requirement to modify grade 2 and 3."

"sorry I asked about this before!"

"Have seen notching associated with instability"

"a) could be defined as mechanical notching and b) as biological notching"

"Scapular notching is transitive! Scapular notch is what we see at the moment of the X-Ray. = loss of scapular neck bone close to the inferior and medial border to the glenosphere. Grad 1 small notch, not reaching the inferior screw"

"Bony on-growth or spur formation of the triceps tendon should be added."



"scapular notching has been assumed to be related to inferior impingement, but newer reverse shoulders have either lateralised glenoid (and either bone or metal) or lateralised via humerus (especially only stem components). Thus whilst notching is 'a thing' for traditional style reverses it cannot measure inferior component mismatch in lateralised joints; we thus need a systematic review of inferior RSA morphology to bring in over time."

"Care should be taken in the judgement of notching in a confusing traction spur of the triceps longus tendon at the undersurface of the glenoid. This spur can mimic notching, however this is not a real gap in the glenoid but a suggestive gap due to extra bone medially."

## Implant wear

Based on a proposal by Prof. Richard Page (Deakin University, GeelongBurwood, VIC, Australia)

Definition : Damage, erosion or loss of surface material of an implant over time, which is identified by reduction of joint space observed on serial plain radiographs.

Specifications :

- a) Articular surface: reduction of joint space observed on serial plain radiographs (concentric or eccentric wear).
- b) Change in position of a prosthesis at:
  - Bone-implant interface (glenoid, humerus)
  - Cement-implant interface (glenoid, humerus)
  - Modular implant interface (eg. humeral head-neck, metaglene-glenosphere)

*Gunther S.B., Graham J., Norris T.R., Ries M.D., Pruitt L. Retrieved glenoid components: a classification system for surface damage analysis. The Journal of arthroplasty 2002, 17(1):95-100*

*Terrier A., Merlini F., Pioletti D.P., Farron A. Comparison of polyethylene wear in anatomical and reversed shoulder prostheses. Bone & Joint Journal 2009, 91:977-982*

Notes

- The ability to determine wear is based on visualising reduction in the joint space or bone resorption (caused by osteolysis) at one or another bony junction - determination on plain radiographs is limited unless the degree of wear is at an advanced stage. The use of CT scanning with metal suppression software is useful to differentiate osteolysis from wear, particularly with polyethylene components. The use of triple-phase bone scans and SPECT CT is helpful to differentiate loosening from wear, particularly around metal-bone interfaces (but this is not possible using imaging alone to differentiate from septic loosening). CT scans, however, cannot be considered in monitoring context of all SA.

- Severity level indicating the radiographic observation as an untoward event: When symptoms (e.g. pain) leading to reoperation or component revision.

	n (%)	
Do you agree with this definition, specifications and terminology?		
	No	2 (3)
	Yes	63 (97)

### Comments or alternative suggestions

"as this complication can be very hard to detect at a point of time when it would be rather easy to intervene surgically and on the other hand this Problem is very implant-specific, it would be important to have an implant specific database of radiological signs of hardware related complications"

"I would agree that the ability to visualize wear on plain radiographs is limited"



"Currently, SPECT CT appears most suitable for specific differential questions. "

"In case of severe metallosis you might see a cloud of synovitis around the joint, which outlines the capsule and its synovitis which contains the radiopaque metal particles "

"should normalized or calibrated XR be used to compare XRs and resultant wear which might indicate amount of wear"

"Need to ensure the use of the terms osteolysis / bone resorption in this definition reflect those used in parameter 4."

"b) is in most cases extremely difficult to Diagnose, mostly after Explantation, could be omitted perhaps"

"The pathogenesis is included in the definition"

"dear Laurent see, here you use osteolysis instead of bone Resorption ,as opposed to the previous page ;-)"

"I would call it WEAR OF THE ARTICULATING SURFACES, because there are other locations where the implant can wear out! especially in complex multipeace, convertible models. I would skip the reason (friction) and I would skip the biological reaction (bone resorption) Migration of the implant has nothing to do with WEAR OF THE ARTICULATING SURFACES"

"This assumes that UHMWPE or variant is the joint space. Newer materials (ceramic on metal or pyrocarbon on bone) have different parameters that need to be considered. For example pyrocarbon is not radio dense and CT can see the entire bone under prosthesis, and whilst not routine may be a monitoring method. As we develop more articulating materials this needs to be accounted for rather than assuming the 'plastic gap' is the thickness of the articulation relative to wear."

## Other radiographic parameters were mentioned

Which of the following other radiographic parameters should be considered as part of a screening protocol?

Other parameters	n (%)
Osteochondral glenoid erosion in hemiarthroplasty	49 (70)
Fractures around the implant (humeral, scapula side)	58 (83)
Implant breakage / dissociation	61 (87)
Bone healing (e.g. in case of osteotomy or tubercle migration)	39 (56)

### Note

Rotator cuff integrity was suggested, however, it cannot be reliably documented using standard radiographs other than via proxy parameters such as humeral head migration in asymptomatic patients.

### Comments or alternative suggestions

"especially glenoid erosion in HA can become a serious problem nearly impossible to solve if it occurs in an eccentric position. Early detection of this complication can save shoulders...."

"superior migration/ acromial erosion in hemi. May be covered by instability but not if glenoid wear remains congruent with humeral head. "

"however antero superior migration can be identified on xray which may indicate subscap failure"

"I do not find purely radiographic fu useful in SA patients. If the patient has symptoms then the radiographs become necessity. "

"Heterotopic ossifications (not heterotopic bone formation) might occur rarely."

"stress fractures of the scapular spine "

"Periosteal reaction (infection)"

"Agree humeral head migration is variable in plain XR What about considering including with the use of ultrasound assessment - which we certainly use in this setting?"

"Various types of bone resorption such as 1. bone resorption in the calcar region in TSA 2. bone resorption at the transition greater tuberosity to shaft (laterally) in TSA and RSA."

"Bone healing is time related as some heal perfectly then resorb ++"



## Radiographic views, quality criteria and schedule

Based on the initial proposal by Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

Standard radiographic views (fluoroscopic positioning is recommended) :	
- True anteroposterior view in 0° abduction and in neutral position (i.e. neutral to the plane of the scapula)	
- Axillary view in 90° abduction or Y-view (e.g. if axillary view cannot be obtained due to limited abduction capacity).	
Monitoring time frame : First set of radiographs within the first week after implantation, a second set at three months and a third set 12 months after implantation.	
<i>Notes</i>	
- The following recommendation stems from the idea that long-term monitoring is only justified if any radiographic observations would lead to an additional intervention(s) before the occurrence of symptoms. There is no evidence suggesting that long-term radiographic monitoring is cost-effective as opposed to performing clinical and radiographic check-up examinations only in patients reporting symptoms. However, a minimum radiographic monitoring regime is warranted to specifically assess short-term parameter progression and should be applicable in all settings.	
- We believe the true AP view in neutral position may be replaced by two views in internal and external rotation, respectively.	
- Other radiographic views such as the Neer outlet view or functional radiographs (e.g. AP view in 60° abduction, axillary view in horizontal flexion as well as extension of the arm) are considered in a diagnostic context only.	

	n (%)	
Do you agree with this proposed minimum radiographic set and timeline?	No	16 (25)
	Yes	49 (75)

### *Comments or alternative suggestions*

"Would be ok with within 2 weeks of surgery and think final X-ray should be 2 years"

"the schedule should be refined according to the indication and type of AP. E.g. fracture case, HemiAP, reverse AP... this could lead to more consensus"

"may not be needed at 3 months if all cemented components, unlikely to shift and asymptomatic.. "

"I do not see a need for standard radiographic screening at 12 mo. The majority of patients will do fine and hence it is a waste of resources"

"for reverse prosthesis AP in 60 degrees of abduction is mandatory to assess notching"

"If axillary view is not possible because of lack of abduction the Velpeau view should be performed. "

"please see the previous. I think postoperative radiographs are sufficient in otherwise uneventful healing and followup."

"I see no value in the 3 month radiograph. Post op and 1 year"

"In my opinion 3 months is too short to recognize bony changes as scapular notching, heterotopic ossification, radiolucency or glenoid erosion. And all other implant associated changes as dissociation or dislocation might be symptomatic. Therefore, I would recommend to perform the second radiographic check after 6 months, which I do in my clinical practice as well, already for a couple of years."

"I do not agree with replacing the true ap with ir and er views; I also think we should attempt a bernageau view as it offers excellent screening of component position "



"Axillary view and additional set at 6 weeks is useful in patients in whom a laser tuberosity osteotomy was performed."

"A true AP (glenohumeral) view combined with a true AP (humeral) view appears helpful."

"Views in internal and external rotation are not helpful in my opinion."

"Regular radiological monitoring is necessary for implant safety survey allowing early detection of preclinical problems."

"We consider radiographic (as well as clinical) monitoring every 1 or 2 years advisable"

"First set of xrays within first week often not of ideal quality due to pain with positioning. "

"X-rax: always three views (AP and axillary view cannot exclude AP instability) I recommend AP, Neer and axial traumatic (no abduction required) 3 months is too late, most short term complications appear during the first 6 weeks."

"Agree with using IR / ER views - which is part of our standard protocol. We would also include an oblique Superoinferior view if true axillary lateral not obtainable. <https://radiopaedia.org/articles/shoulder-modified-trauma-axial-view> "

"Happy with timeline. i have no experience of replacing the AP view by two views internal and external. If an axillary view cannot be obtained a STRIP view is a very good second best and MUCH better than a Y view. We use the STRIP view regularly for our fractures as it can be done with the arm by the side. I agree about having two views but would want an axillary or STRIP view not a Y lateral"

"!2 month control is unnecessary."

"true ap must be more precisely defined as neutral Rotation of the Humerus and perpendicular to the Joint line axillary is preferred over y-view"

"Regional and national differences in preferred radiographic views can be found. In my country axillary views are rarely used."

"I would always consider their Neer view too"

"I stumble of the word true AP. Nothing is true about the true AP! In fact we need a false AP of the proximal humerus (corrected for its retrotorsion) and a false AP of the scapula, corrected for its tilt (= flexion) and is internal rotation. "

"We routinely do one week, six weeks, three months and one year. I would recommend that in particular in reverse shoulder arthroplasty as a revision procedure the monitoring should include another follow-up between the first week and the three month evaluation since the risk of instability is higher."

"I agree in general but would only review patients at 3 months with radiographs in trauma, complex or revision cases particularly when osteotomies and / or bone grafting has been used."

"The retroversion of the humeral component in the case of an anatomical prosthesis varies between +5 and -50 degrees (in reverse the position is fixed in e.g. 0 or -20). An AP view of the shoulder for monitoring should imply an AP view of the glenoid, but also of the humerus. So the view must be AP to the humeral component. The first X-rays can be made in ext/neutral/int rotation in order to conclude what the desired position is for a true AP humeral view in that specific shoulder. If this position is stored on the X ray, the next time the X ray can be made in the same arm position to optimise the reproducibility in that shoulder. In shoulder prostheses survey the Bernageau view is very useful as axillary view."



## File 8 SA Radiological Monitoring v1.0 - Delphi 03 survey results – June 2018

### SA Radiological Monitoring v1.0

#### Core list of radiological parameters for shoulder arthroplasty (SA) monitoring

#### Delphi 03 survey results

#### June 2018

Note : Modifications to the Core Set that were decided by the Steering Committee on the basis of these results are presented in red in the text below.

#### Implant migration (e.g. subsidence, tilt, shift)

Based on a proposal by Dr. Bjorn Salomonsson (Karolinska Institutet Danderyds Sjukhus AB, Stockholm, Sweden)

Definition of terms : Implant migration is a noticeable change of the position of the implant, relative to the bone it is supposedly fixed to (either cemented or uncemented).

Specifications :

**Implant migration is documented separately for the humeral and glenoid components.**

- **Subsidence** : migration of the implant along a linear axis compared to the immediate post implantation position documented in one of 3 classes:

None = no sign of subsidence

Suspicion = subsidence is suspected but with no more than 5 mm of migration

Definite = subsidence is noted with more than 5 mm of migration

- **Tilt** : migration of the implant resulting in an angulation of its main axis compared to the immediate post implantation position documented in one of 3 classes:

None = no sign of tilt

Suspicion = tilt is suspected but with no more than 10° of angulation

Definite = tilt is noted with more than 10° of angulation

- **Shift** : migration as a combination of subsidence and tilt. Shift is suspected when both subsidence and tilt are suspected or one is suspected and the other is definite. Shift is definite when both subsidence and tilt are definite.

*Brinke B.T., Beumer A., Koenraadt K.L.M., Eygendaal D., Kraan G.A., Mathijssen N.M.C. The accuracy and precision of radiostereometric analysis in upper limb arthroplasty, Acta Orthopaedica 2017, 88(3):320-325*

*Streit J.J., Shishani Y., Greene M.E., Nebergall A.K., Wanner J.P., Bragdon C.R., Malchau H., Gobeze R. Radiostereometric and radiographic analysis of glenoid component motion after total shoulder arthroplasty, Orthopedics 2015, 38(10):e891-e897*

*Valstar E.R., Gill R., Ryd L., Flivik G., Börlin N., Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants, Acta Orthopaedica 2005, 76(4):563-572*

#### Notes

- We suggest subsidence of a humeral implant can be measured relative to the highest point of the greater tubercle (but not if it is the tubercle that migrates), and a medial migration of the glenoid component relative to the base of the coracoid on AP radiographs of the shoulder. Tilt of the humeral component can be measured relative to the mid-shaft line of the humerus. Tilt of the glenoid component can be measured relative to the plane of the under-surface of the acromion.



- We accept that in some situations, the defined reference points (greater tuberosity or acromion) may not be adequate for the measurement of the respective migration parameters.
- Severity level indicating the radiographic observation as an untoward event: Implant migration is of interest in the evaluation after shoulder arthroplasty, mainly as an indication of possible loosening or malposition that is to be regarded as a complication after the joint replacement. However, implant migration without any clinical symptoms or deterioration of function is not specifically defined as a complication, but may indicate a need of future monitoring of the implant. Infection and loosening may be events associated with implant migration, but these causes should be considered higher in the hierarchy of complications compared to migration.
- A suspicion of subsidence, tilt or shift may lead to further diagnostic by CT scans.
- Implant migration may have different patterns. Early migration during settling in the first months, followed by a stable situation is normal for some types of implants, especially uncemented implants are reported to settle before fixation. Contrary a continuous migration without stabilization is considered to be a not fixed implant. Initial stability followed by later migration should be considered as a sign of loosening of the implant. However, also a loose implant may be without migration on subsequent radiographs.
- Implant migration do not include complications related to failure of the implant by breakage, dissociation, disassembly or articular dislocation. Also cement fractures or cement migration is not included in implant migration, but could be indications of loosening.
- Implant migration do not include translation relative to other bony structures than the one where the implant is supposed to be fixed, e.g. a humeral implant is not considered to be migrated relative to the glenoid (glenoid erosion or wear) or acromion (cuff deficiency). Neither is a migration of tubercles (e.g. after a fracture arthroplasty) defined as an implant migration.
- Implant migration do not include change of the bony structure by stress shielding, osteolysis or radiolucent lines, without any change of the absolute position of the implant in relation to the main bone structure.
- For research the RSA method is the gold standard to measure implant migration, but this is usually not feasible for clinical routine monitoring. For clinical monitoring of implant migration plain radiographs in neutral position of rotation in AP view is the most informative examination.
- Implant migration is a change of position (of the implant) that occurs over a period of time between subsequent radiographic examinations. It is not a malposition noted direct postoperatively. If motion of the implant is noted during an examination, as during provocation, then the implant instead is to be considered to be loose.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	4 (6)
	Yes	65 (94)

#### *Comments or alternative suggestions*

"Yes, but it is also necessary to relate the measures to the accuracy of the tool to measure with. perhaps the cut offs should be defined as for plain radiographs? Any given situation where there is undisputed observation of Subsidence, Tilt or Shift, then a definite Implant migration is present, if the change of position is observed larger than the limits of the measurement errors, of the measurement method used."

"5 mm seems like a lot. 2 mm may be better"

"Shift can be defined as any migration not purely along the linear axis."

"The cut-off at 5mm between suspicion and definite subsidence is unclear to me. I think the threshold should be lower i.e. 3mm"

"Definitions OK but I would stay with >1mm subsidence and 5° tilt"



## Radiolucency around the implant / Implant loosening

Based on a proposal by Dr. John Sperling (Mayo Clinic, Rochester, Minnesota, USA) and Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

### Definition of terms :

Radiolucency relates to the occurrence/observation of radiolucent lines (RLL) at the bone-implant, bone-cement or cement-implant interface.

Implant loosening is considered when respective components are identified with Grade 2b lucency (see below) or a shift in position (see previous section) between postoperative radiographs (implants at risk of failure based on radiographic outcome).

### Specifications :

RLL are documented according to their presence or absence, location and thickness, separately for the humeral and glenoid components. The humeral component is further divided into metaphysis and diaphysis according to the surgical neck of the humerus (~~visible on standard radiographs~~).

Within each of these locations (as appropriate for various prosthesis types), the severity of RLL occurrence is graded in one of 5 categories as follows:

Grade 0 : None (no clear sign of RLL)

Grade 1 : Incomplete RLL (radiolucency not all around the implant)

- a. no line reaching 1.5mm in width
- b. at least one RLL reaching 1.5mm or more in width

Grade 2 : Complete radiolucency around the implant

- a. not reaching 1.5mm in width
- b. reaching 1.5mm or more in width (loosening)

*Sperling J.W., Cofield R.H., O'Driscoll S.W., Torchia M.E., Rowland C.M. Radiographic assessment of ingrowth total shoulder arthroplasty. J Shoulder Elbow Surg 2000, 9(6): 507-513*

*Schoch B.S., Barlow J.D., Schleck C., Cofield R.H., Sperling J.W. Shoulder arthroplasty for post-traumatic osteonecrosis of the humeral head. J Shoulder Elbow Surg 2016, 25(3):406-412*

### Notes

- Severity level indicating the radiographic observation as an untoward event: development of symptoms, implant loosening (Grade 2b lucency) and/or revision of arthroplasty.
- Loosening could be aseptic or due to infection. In the latter case, infection is the leading adverse event.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	1 (1)
	Yes	67 (99)

### Comments or alternative suggestions

"Yes, but again it is also necessary to relate the measures to the accuracy of the tool to measure with. perhaps the cut offs should be defined as for plain radiographs? Any given situation where there is undisputed observation of RLL, then the grading could be done. And if the RLL is observed including the measurement errors, of the measurement method used."

"It is unclear what '4' refers to in 'Grade 2b4'."

"Radiolucency can be very difficult to detect. I think it is mandatory to have signs of radiolucency in at least two different follow-up appointments"

"0,5 mm is too low to identify in common practice I'll stay with whole number"



## Signs of ~~shoulder joint displacement~~ ~~shoulder instability~~

Based on a proposal by Dr. Philipp Moroder (Charité Universitätsmedizin Berlin, Germany)

Definition of terms : Shoulder ~~joint displacement~~ ~~instability~~ refers to a loss of alignment of the articulating surface of the humeral component with the articulating surface of its joint partner.

Specifications :

- Subluxation ~~Static instability~~: non-arm position-dependent eccentric misalignment of the articulating surfaces with residual contact visible on standard radiographs.

- Dislocation: non-arm position-dependent complete loss of contact of the articulating surfaces visible on standard radiographs.

When present, the direction of ~~subluxation~~ ~~instability~~ or dislocation is noted from the AP view (superior / inferior) as well as from the axillary view or Y-view (anterior / posterior).

*Merolla G, Di Pietto F, Romano S, Paladini P, Campi F, Porcellini G. Radiographic analysis of shoulder anatomical arthroplasty. Eur J Radiol 2008;68:159-169.*

Notes

- Dynamic instability (arm position-dependent loss of contact) requires functional radiographs (horizontal flexion/extension view in 90° of abduction or otherwise, if that cannot be achieved by the patient, internal and external rotation AP view in 0° of abduction, as well as true AP view in 60° of abduction) and therefore, cannot be documented in routine monitoring of asymptomatic patients using standard radiographs. Functional imaging is recommended only in the case of clinically suspected dynamic instability (i.e. in the presence of symptoms). This event is therefore addressed in the Core Event Set.

- Severity level indicating the radiographic observation as an untoward event: A dislocation is considered an adverse event/complication regardless of symptoms or required revision surgery. Subluxation ~~Static~~ and dynamic instability are only considered as adverse events/complications in the presence of symptoms or required revision surgery due to eccentric component wear or bone loss.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	10 (15)
	Yes	57 (85)

### Comments or alternative suggestions

"Definition of instability is excessive translation of the shoulder joint associated with symptoms (pain, subluxations, dislocation). The mix with static subluxation seems inappropriate"

"'Instability', strictly speaking, is a dynamic phenomenon Therefore 'static instability' is a contradiction in terms! (I however agree it comes under the umbrella of instability for descriptive purposes, but I disagree with proposed terminology based on static images) Static images would indicate degree of joint displacement - better to word these as 'subluxation' and 'dislocation' based on static images".

"I would write: **static instability**: non-arm position-dependent eccentric misalignment of the articulating surfaces with residual contact visible on standard radiographs.

**dislocation**: non-arm position-dependent complete loss of contact of the articulating surfaces visible on standard radiographs. Shouldn't the note be added that dynamic instability is not covered by standard radiographs?"

"Should we also consider/add 'dynamic instability': arm position-dependent eccentric misalignment with residual contact visible on standard radiographs e.g. alignment appears normal on IR AP radiograph, but displaced/misaligned on neutral rotation AP radiograph, in cases where some but not all of the rotator cuff is failing or failed"

"The axillary view is not possible in all cases - why don't you additionally the Y-view. It is also added in the standard x-rays in the following pages. There ant/post is mostly also visible."



"You can't really restrict this to dislocation and static, as the commonest cause of reoperation is subluxation due to Subscap failure, and plain films don't show this well (unless it is static). Maybe needs a rider comment re special studies in specific cases."

"I think you should include a Bernageau view for TSA instability "

"I feel there is a place for dynamic instability. An x-ray may be normal when taken at time of review and hence be classified as 'stable' / concentric. But if a joint repeatedly dislocates and is reduced back into joint and is radiologically reduced should it then be classed as stable at the time of review. My thoughts are it is relevant to me if a patient is

- Grade 1 dynamic unstable - aware of the sensation of instability but does not dislocate, has normal x-rays and does not require revision.
- Grade 2 dynamic unstable - the patient has dislocated once, reduction has been achieved closed or open without need to revise components
- Grade 3 dynamic unstable - the patient has dislocated and reduction and stabilisation requires revision of some component.
- Grade 4 dynamic unstable revision surgery has been performed and the shoulder continues to dislocate
- Grade 5 dynamic unstable - revision of revision to excision arthroplasty or fusion"

"Agree - but need to emphasize for anatomic/conventional total shoulder arthroplasty"

"is there going to be a positional dependent instability definition?"

"What do we do with patients who are centered on true a/p views but decenter anteriorly with axillary imaging? This is in my eyes static instability but it is dependent on the abduction position of the arm for the axillary view"

"I think it should include Scapular Y view as well as axillary view may not be possible to perform in cases of dislocation"

"Shoulder instability refers to a clinical symptom and is not a good term to describe a radiographic diagnosis. On an x ray, an observer would assess whether the Joint is centered or not"

## Bone resorption / Bone formation

Based on a proposal by Dr. Simon Lambert (University College London Hospital, London, UK)

### Definitions :

Bone resorption: the progressive disappearance of bone from the humerus and/or scapula following SA when compared to the immediate post-operative condition. **Bone resorption includes scapular notching and osteochondral erosions.**

Bone formation: the progressive apposition of bone on or in the humerus and/or scapula following SA when compared to the immediate post-operative condition, more than that required for stable integration of the prosthesis.

- Orthotopic bone formation (ossification) is bone formation within the confines of the bone including the periosteum: bone is formed within tissue that is destined to be or become bone under normal healing or loading conditions.
- Heterotopic bone formation (ossification) is a subset of excess bone formation within or between tissues that is not destined to be or become bone under normal healing or loading conditions.

### Specifications :

Bone region-based description of periprosthetic occurrence / extent of bone resorption / formation:

- Humeral side: further divided into metaphysis and diaphysis according to the surgical neck of the humerus (**visible on standard radiographs**). When **bone resorption** is located above the surgical neck, the involvement of the calcar region and/or the tuberosities is documented.
- Glenoid side (without further division)

Heterotopic bone formation is classified according to **a modified the** Brooker classification\*\*

**\*\*Brooker AF, Bowerman JW, Robinson RA, Riley Jr LH. Ectopic ossification following total hip replacement: incidence and a method of classification. JBJS 1973;55:1629-1632.**



#### Notes

- Scapular notching specific to reverse SA is a form of glenoid-side bone resorption and is classified according to the Nero-Sirveaux classification as presented in the next section.
- The terms osteopenia (diminished bone quality or density) and osteolysis (absent bone) may be considered synonyms that should be avoided, since they imply an observation at a specific point in time rather than a progressive disease. The term osteolysis is often used in association with more actively destructive bone loss such as that seen in oncological disease or fulminant infection, where the disequilibrium between bone destruction and bone formation favours the former. It is a subset of bone resorption. However, the term osteolysis is often used indiscriminately and does not always imply active destruction. In this sense, the term is unhelpful. We suggest that bone resorption is the more useful term, since it actually describes what is seen on imaging and in histology but does not imply or define a specific disease process.
- Radiographic features show absence or hypo-density of bone previously present or of normal quality (manifest as "lucent lines", loss of bone structure or density, loss of bone mass), yet detection in a series of radiographs is poorly reliable. Radiographic screening in asymptomatic patients can raise suspicions of bone resorption; CT imaging should be used to confirm bone resorption status in symptomatic patients.
- Severity level indicating the radiographic observation as an untoward event: In the presence of symptoms or required revision surgery due to associated implant loosening.

#### Scapular notching (specific to reverse SA)

Definition of terms : Scapular bone resorption with disruption of the normal contour (= notch) near the glenoid base plate.

Specifications : Classification of the extent of glenoid erosion according to the Nerot-Sirveaux classification\*.

Grade 1 = notch limited to the scapular pillar

Grade 2 = notch reaching the inferior screw of the base plate

Grade 3 = notch extending beyond the inferior screw

Grade 4 = notch reaching the base plate central peg.

\* Valenti P, Boutens D, Nerot C. Reversed prosthesis for osteoarthritis with massive rotator cuff tear: long-term results ( $\geq 5$  years). In: Walch G, Boileau P, Molé D, editors. *Prothèses d'épaule... recul de 2 à 10 ans*. Montpellier, Paris, France: Sauramps Medical; 2001. p. 253-259.

Sirveaux F., Favard L., Oudet D., Huquet D., Walch G., Mole D. Grammont inverted total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis with massive rupture of the cuff. Results of a multicentre study of 80 shoulders. *J Bone Joint Surg Br* 2004; 86(3): 388-95.

#### Notes

- Scapular notching is caused by contact / impingement of the cup of the humeral component and the inferior bone of the scapula and polyethylene wear particles triggering osteolysis.
- The Sirveaux classification system has some limitations due to the variety of prosthesis designs and its dependency on the placement of the inferior screw of the base plate, yet we are not aware of a better alternative for documentation. This system currently remains widely accepted and used.
- Severity level indicating the radiographic observation as an untoward event: When the progression of notching is associated with implant breakage (e.g. screw), or symptomatic implant loosening or migration, or implant revision.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	0
	Yes	65 (100)



### Comments or alternative suggestions

"The statement: '...polyethylene wear particles triggering osteolysis.' in Notes should be supported by a reference."

"How do we interpret spur formation at the inferior glenoid (i.e. traction spur of triceps)?"

"Classification note that it is modified Brooker - as the classification itself relates to the hip"

## Osteochondral erosions

(as another form of bone resorption **now moved into this section**)

Definition : Abrasion of bone and / or cartilage caused by friction with a prosthesis component.

Specifications :

Glenoid erosion (only for hemi-arthroplasty) :

- Eccentric : occurrence of localized glenoid rim erosion
- Concentric : humeral head centered without localized glenoid rim erosion

Erosion of the acromion (only for anatomical hemi and total arthroplasty): concave deformity of the acromion undersurface (acetabularization).

## Wear of the implant articular surfaces

Based on a proposal by Prof. Richard Page (Deakin University, Geelong, VIC, Australia)

Definition : Damage, erosion or loss of the articular surface material over time, which is identified by reduction of joint space observed on serial plain radiographs.

Specifications : Eccentric / Concentric

**When Eccentric, the wear location is noted from the AP view (superior / inferior) as well as from the axillary view or Y-view (anterior / posterior).**

*Gunther S.B., Graham J., Norris T.R., Ries M.D., Pruitt L. Retrieved glenoid components: a classification system for surface damage analysis. The Journal of arthroplasty 2002, 17(1):95-100*

*Terrier A., Merlini F., Pioletti D.P., Farron A. Comparison of polyethylene wear in anatomical and reversed shoulder prostheses. Bone & Joint Journal 2009, 91:977-982*

### Notes

- Wear is usually due to friction between material surfaces. Biologically active particles generate an inflammatory response that may result in bone resorption and/or loss of fixation of the implant. This assumes that the joint space includes a material such as metal articulating with another such as polyethylene or bone. Alternative articulating materials exist (e.g. pyrocarbon or ceramic on bone), however their wear characteristics are less well described in the shoulder.

- The ability to determine wear is based on visualising reduction in the joint space or bone resorption (caused by osteolysis or abrasion) at one or another bony junction - determination on plain radiographs is limited unless the degree of wear is at an advanced stage, but sequential standardised radiographs may demonstrate changes over time, so be useful for monitoring. The use of CT scanning with metal suppression software is useful to differentiate osteolysis from wear, particularly with polyethylene components. The use of triple-phase bone scans and SPECT CT is helpful to differentiate loosening from wear, particularly around metal-bone interfaces (but this is not possible using imaging alone to differentiate from septic loosening). CT scans, however, cannot be considered in monitoring context of all SA.

- Severity level indicating the radiographic observation as an untoward event: When the reduction in joint space is associated with symptoms (e.g. pain) leading to additional treatment.



	n (%)	
Do you agree with this definition, specifications and terminology?		
	No	2 (3)
	Yes	62 (97)

#### *Comments or alternative suggestions*

"I believe that: 'Biologically active particles generate an inflammatory response including osteolysis that may result in bone resorption and/or loss of fixation of the implant.' Might not be a definition of 'Wear', but a possible explanation of the result that is possible to see on radiographs, and the effect of 'wear'?"

"Perhaps... 'Damage, erosion....friction. Bone resorption, radiolucent lines (RLL) and/or radiological evidence of loosening of the implant(s) may follow.' This keeps the definition to what can be seen on radiographs, rather than bring in pathological processes (which we have to infer), and stays with definitions previously used for the other parameters of SA complications (bone resorption, RLL, and loosening)."

"Should it be subdivided into glenoid side wear and humeral side wear? Also grading the amount of wear as 1 visible but not in need of revision, can be observed 2 significant wear requiring revision eg if eg poly wear is down to metal / base plate / humeral stem"

"Head of the implant centered or not centered in the socket. Is that concentric/excentric means here?"

"doesn't specify how determined - XR vs fluoro vs limited MRI vs CT"

"When eccentric the position of the wear should be documented (anterior, posterior etc)"

"Excellent! Potential reference: Wear in the Prosthetic Shoulder: Association With Design Parameters. Andrew R. Hopkins, Ulrich N. Hansen, Andrew A. Amis, Lucy Knight, Mark Taylor, Ofer Levy and Stephen A. Copeland. J Biomech Eng 129(2), 223-230 (Oct 04, 2006) (8 pages) doi:10.1115/1.2486060"

#### Fractures around the implant

##### **Specifications :**

##### **Humeral fracture:**

- Tubercula
- Sub-capital, at the surgical neck (stemless prosthesis)
- Diaphysis spiral / transverse (stemmed ~~shaft~~ prosthesis)
- Distal (below the shaft)

##### **Scapula fracture:\***

- Body
- processes (spine, acromion, coracoid)
- Glenoid neck
- Articular (glenoid rim, fossa)

*\*Euler E, Rüedi T. Scapulafraktur. In: Schulterchirurgie, edited by Habermeyer P, Schweberer L, 2nd edition Urban & Schwarzenberg, München, Wien, Baltimore, 1996; 261-272.*



*Notes:*

- A number of classification systems for peri-prosthetic humeral fractures were in use (Campbell et al, Wright and Cofield, Groh et al, Worland et al), however they were developed for shaft prosthesis to support further treatment algorithms\*. This is beyond the objective of this monitoring process, which should primarily document the fracture location.

- Peri-prosthetic humeral fractures may occur because of trauma or loosening of the implant\*\*.

\* Kirchhoff C, Kirchhoff S, Biberthaler P. [Classification of periprosthetic shoulder fractures]. *Der Unfallchirurg* 2016; 119:264-272.

\*\*Andersen JR, Williams CD, Cain R, Mighell M, Frankle M. Surgically treated humeral shaft fractures following shoulder arthroplasty. *The Journal of bone and joint surgery American volume* 2013;95:9-18.

## Implant breakage / disassembly

**Definitions :**

- Implant breakage : one part of the prosthesis is broken

- Implant disassembly : noticeable change of the relative position of the various parts of an implant humeral or glenoid component

Specifications : Humeral side / Scapula side

*Note:*

Rotator cuff integrity was suggested, however, not further considered as it cannot be reliably documented using standard radiographs other than via proxy parameters such as humeral head migration in asymptomatic patients.

	n (%)	
Do you agree with this definition, specifications and terminology?	No	1 (2)
	Yes	63 (98)

*Comments or alternative suggestions*

"Suggestion Fractures around the implant: Humeral fracture - I agree Scapular fracture - articular segment: glenoid rim, glenoid fossa, glenoid neck; - processes: acromion; acromiospinal; coracoid - body"

"In periprosthetic fracture may be useful to include if well fixed or loose at time of fracture as per Vancouver in hips. a fracture and failure is a failure and depends if classification is simply to look at failures or whether it is to help classify and guide revision procedure"

"The concept of stress shielding is not included in the radiographic evaluation. Please see this current concept review paper: Denard PJ, Raiss P, Gobeze R, Edwards TB, Lederman E. Stress shielding of the humerus in press-fit anatomic shoulder arthroplasty: review and recommendations for evaluation. *Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons* [et al]. 2018 Feb 5. "

"Though note a true 'fracture around the implant', it may be worthwhile to identify and categorize acromial stress fractures in reverse TSA"

"I prefer the term 'stemmed prosthesis' to 'shaft prosthesis' especially when 'stemless prosthesis' is mentioned above."



## Radiographic views, quality criteria and schedule

Based on the initial proposal by Dr. Holger Durchholz (Clinic Gut St Moritz, St Moritz GR, Switzerland)

Standard radiographic views (fluoroscopic positioning is recommended) :

- True anteroposterior view in 0° abduction and in neutral position (i.e. ~~parallel to the glenoid surface neutral to the plane of the scapula~~)
- Axillary view in 90° abduction with the humerus in linear alignment with the scapular body (i.e. perpendicular to the glenoid) or Y-view (e.g. if axillary view cannot be obtained due to limited abduction capacity).

Monitoring time frame : First set of radiographs within the first six weeks after implantation, a second set ~~at three months~~ **between 3 and 6 months** and a third set 12 months after implantation.

### Notes

- This standard monitoring applies for asymptomatic patients
- The following recommendation stems from the idea that long-term monitoring is only justified if any radiographic observations would lead to an additional intervention(s) before the occurrence of symptoms. There is no evidence suggesting that long-term radiographic monitoring is cost-effective as opposed to performing clinical and radiographic check-up examinations only in patients reporting symptoms. However, a minimum radiographic monitoring regime is warranted to specifically assess short-term parameter progression and should be applicable in all settings.
- In the early postoperative phase (the first two weeks) it is very difficult to obtain a reproducible series of radiographs of the operated shoulder (pain, movement inhibition, etc).
- We believe the true AP view in neutral position may be replaced by two views in internal and external rotation, respectively.
- Other radiographic views such as the Neer outlet view, the Stripp view or functional radiographs (e.g. AP view in 60° abduction, axillary view in horizontal flexion as well as extension of the arm) are considered in a diagnostic context only.

	n (%)	
Do you agree with this proposed minimum radiographic set and timeline?	No	14 (22)
	Yes	50 (78)

### Comments

"Monitoring time Frame: -within the first six weeks -second after six months -third after 12 months that is the way I practise "

"I would also suggest ideal radio graphic follow up yearly for first 5 years then then every two years for the next six years then every five years This will encourage longer and more robust radio graphic follow up information"

"I suggest: True anteroposterior view in 0° abduction and in neutral position (i.e. parallel to the glenoid surface)"

"I think you should mandate a Bernageau view "

"Y-View should always be part of the radiographic workup and axillary view where needed"

"I would get intra op or at least recovery room x-rays. Six weeks is too long if there is anything wrong"

"First set of radiographs within the first six weeks and second set at 12 months."

"6 Month, 2 years"

"why not further times noted as well due to need to long term surveillance (its our duty). postop, 6 mo, 1 yr, 2 yr, 5 yr, 10 yr"

"Three months not strictly necessary"



"Do we know if the 6 month follow-up is beneficial to evaluate?"

"Second set should be done within six months as minimum data set collection for National joint registry is at six months interval . In UK, whilst working in NHS we are being encouraged to do a routine review at six months after initial review unless there is a specific problem."

"I think post op and 1 Year are enough for the non- symptomatic patient. And there is no therapeutic action to take in an asymptomatic patient at 3 months post OP"

"post op views of Reverse needs to be taken in 45 degrees abduction otherwise notching cannot be seen. In immediate post op phase axillary view not possible so modified or Nottingham view appropriate. First x-ray should be the following day after surgery."

"Not sure that 3 months necessary unless intra-operative or early post op issues Otherwise agree"

"I do not see a 3 mo set required as part of a standardised schedule"

"I will add a set of radiographs at six months"

"Strict lateral view of implants need to be emphasized! Like true ap with strict lateral view of prosthetic implants. Arm rotation is no so important."