


# OMERACT Definitions for Ultrasonographic Pathologies and Elementary Lesions of Rheumatic Disorders 15 Years On

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**ABSTRACT. Objective.** The Outcome Measures in Rheumatology (OMERACT) Ultrasound (US) Working Group (WG) operates research activities for the validation of US as an outcome measurement instrument according to the Filter 2.0 framework.

**Methods.** Original publications on definitions and scoring systems for pathophysiological manifestations and elementary lesions of various rheumatic disorders were reviewed from the onset of the WG research in 2005.

**Results.** Definitions and scoring systems according to new terminology are provided.

**Conclusion.** We have redefined OMERACT US pathology and elementary lesions as well as scoring systems, which are now proposed for OMERACT approval for application in clinical trials. (First Release April 15 2019; J Rheumatol 2019;46:1388–93; doi:10.3899/jrheum.181095)

## Key Indexing Terms:

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DEFINITIONS

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Since their introduction in 2005<sup>1</sup>, provisional ultrasound (US) definitions have become part of the fundamental Outcome Measures in Rheumatology (OMERACT) methodology for developing and validating US as a disease outcome measurement instrument (OMI) across various domains including inflammatory burden and structural damage<sup>2,3</sup>.

In a seminal paper, the OMERACT Ultrasound (US) Working Group (WG) described 6 provisional definitions of US lesions considered to represent an “US core set” of pathophysiological manifestations in rheumatic diseases<sup>1</sup>. The definitions were truly provisional, as at that time, a concurrent systematic literature review (SLR) highlighted the lack of consensus-based definitions in the existing literature<sup>4</sup>.

Since then, iterative validation exercises have repeatedly shown US to be a reliable OMI for measuring (ir)reversible pathophysiological manifestations of rheumatoid arthritis (RA), i.e., synovitis, tenosynovitis<sup>5,6,7</sup>, or erosions. Further, the OMERACT US WG has engaged in the validation of US as an OMI by defining US manifestations of rheumatic disorders other than RA, including osteoarthritis, spondyloarthritis (SpA), psoriatic arthritis (PsA), crystal-related arthropathies, large vessel vasculitis, Sjögren syndrome, systemic lupus erythematosus (SLE), as well as in juvenile inflammatory arthritis. The validation process not only resulted in a refinement of the original US definitions for RA pathologies but also in defining new disease-associated pathologies and corresponding elementary lesions.

This report provides an overview of the WG activities and presents the new US definitions and scoring systems for synovitis, enthesitis, tenosynovitis, and tendon damage.

### Updated Definitions

**Synovitis.** Rather than defining a single entity, the initial definition included 2 elementary lesions, synovial effusion, and synovial hypertrophy. Either one, separate or combined, could indicate synovitis<sup>1</sup>.

Following a stepwise validation process that consisted of a Delphi exercise for developing consensual definitions of pathology and elementary lesions, Web-based and patient reliability exercises testing systematically the validity and the reliability of those lesions<sup>6,7</sup>, a sub-task force of the OMERACT US WG concluded that the old definition of synovitis was not sustainable. The “new” definition of an US-detected synovitis encompasses the whole concept of synovitis, thereby delineating synovial hypertrophy (SH) in a semiquantitative graded B mode feature and a graded Doppler mode feature. The presence of a hypoechoic SH is mandatory for defining the presence of an US-detected synovitis and for grading Doppler activity. Further, the new definition lacks the elementary lesion “synovial effusion,” because it did not prove reliable and was frequently detected in healthy subjects<sup>6,7,8</sup>. In addition, the group developed a synovitis scoring system<sup>6,7</sup> combining B mode and Doppler mode, which demonstrated sensitivity to change in small and large joints<sup>9</sup>. The new synovitis definition is presented in Table 1, and the new definition of the related elementary lesions is reported in Table 2. The combined European League Against Rheumatism (EULAR)-OMERACT scoring system is reported in the Supplementary Table 1 (available with the online version of this article).

**Enthesitis.** Whereas the provisional US definition spoke of enthesopathy<sup>1</sup>, this term is now singled out exclusively for a mechanically related enthesopathy including sports-related activities<sup>10,11</sup>.

Based on an SLR, a high variability was found in the definition of enthesitis, and in particular its constituent elementary components, and no consensus-based scoring existed<sup>10</sup>. This inhomogeneity resulted in an appropriate task force to work on the development of a validated definition of enthesitis, using the same methodology described for developing synovitis<sup>11,12</sup>. The final definition of enthesitis is shown in Table 1 and can be used in SpA and PsA, along with the elementary lesions that should be detected for defining such a pathological entity (Table 2) and the scoring system to use for grading these elementary lesions<sup>12</sup>. The scoring of Doppler was further refined in a recent Delphi exercise (unpublished data) obtaining > 75% consensus on a semiquantitative scoring 0–3 (Supplementary Table 2, available with the online version of this article).

**Tenosynovitis and tendon damage.** Following the same systematic stepwise process, the OMERACT US WG conducted a series of formal Delphi studies and reliability exercises on elementary lesions of tenosynovitis and tendon damage, resulting in new definitions of tenosynovitis and related elementary lesions (Table 1 and Table 2), as well as 2 scoring systems, one for tenosynovitis and one for tendon damage (Supplementary Table 3, available with the online version of this article)<sup>13,14</sup>. Tendon damage is a structural lesion and solely defined in B mode, because this mode allows the evaluation of the morphology. Criterion validity of the tendon damage definition was demonstrated in cadavers<sup>15</sup>. The new definition of tenosynovitis includes changes in B mode and Doppler mode and has shown sensitivity to change in patients with RA<sup>16</sup>.

**Bone erosion.** The original OMERACT definition of bone erosion spoke of “an intraarticular discontinuity of the bone surface that is visible in two perpendicular planes”<sup>1</sup>. Because no new definition has been developed, this definition is still valid (Table 1)<sup>17</sup>. Future research will focus on distinguishing “true” RA erosions from other cortical breaks, e.g., vessel channels.

**Osteoarthritis (OA).** Initial activities on OA started as a joint venture between the OMERACT US WG and Osteoarthritis Research International and were mainly focused on structural abnormalities in hand OA. By testing the reliability of US in defining and grading cartilage lesions and osteophytes, the group produced a dichotomous and a 4-grade semiquantitative score for cartilage damage and osteophytes, respectively (Table 2; Supplementary Table 4, available with the online version of this article)<sup>18,19</sup>. Following the work on hand OA, the group targeted other joints<sup>20</sup>.

**Juvenile idiopathic arthritis (JIA).** Before defining synovitis in children, the JIA task force developed and validated defini-

Table 1. New OMERACT definitions of US-detected pathologies.

Type	Description
Synovitis	Presence of a hypoechoic synovial hypertrophy regardless of the presence of effusion or any grade of Doppler signal.
Enthesitis	Hypoechoic and/or thickened insertion of the enthesis close to the bone (within 2 mm from the bony cortex) which exhibits Doppler signal if active and that may show erosions, enthesophytes/calcifications as sign of structural damage.
Tenosynovitis	Abnormal anechoic and/or hypoechoic (relative to tendon fibers) tendon sheath widening, which can be related both to the presence of tenosynovial abnormal fluid and/or hypertrophy. Doppler signal can be considered if seen in 2 perpendicular planes, within the peritendinous synovial sheath, excluding normal feeding vessels (i.e., vessels at the mesotenon or vinculae or vessels entering the synovial sheath from surrounding tissues). Doppler mode should be used only if the tendon shows peritendinous synovial sheath widening on B mode.
Tendon damage	Internal and/or peripheral focal tendon defect (i.e., absence of fibers) in the region enclosed by tendon sheath, seen in 2 perpendicular planes; the grade of tendon damage should be assessed in both planes.
Erosion	Intra- and/or extraarticular discontinuity of bone surface (visible in 2 perpendicular planes).
Pediatric synovitis	Presence of hypoechoic synovial hypertrophy or of abnormal synovial effusion.

OMERACT: Outcome Measures in Rheumatology; US: ultrasound.

tions of normal joint components for different age groups through a Delphi consensus process and by testing them in a reliability exercise involving healthy children<sup>21,22,23,24</sup>. In contrast to the definition of synovitis in adults, the US definition in children also includes synovial effusion<sup>25</sup>. The combined scoring system for synovitis using B mode and PD mode is presented in Supplementary Table 5 (available with the online version of this article).

*Gout.* Following an SLR<sup>26</sup>, the group conducted a Delphi exercise with the aim of obtaining and defining the elementary components of the gouty joint<sup>27</sup>. Four definitions of elementary lesions were highlighted, i.e., double contour, aggregates, tophus, and erosions (Table 1 and Table 2), and subsequently tested for reliability in a patient-based exercise<sup>28</sup>. Future work will determine whether these elementary lesions are reliable in the development of a scoring system.

*Calcium pyrophosphate crystal deposit (CPPD) disease.* Although no therapeutic drugs have been specifically developed for treating CPPD disease, the WG felt that CPPD-related arthritis may be a confounding pathological manifestation. Following the OMERACT methodology, definitions of the US characteristics of CPPD at the level of fibrocartilage of the knee menisci and wrist, hyaline cartilage, tendons, and synovial fluid of the knee were obtained (Table 2; Supplementary Table 6, available with the online version of this article)<sup>29</sup>. Subsequently, a series of reliability exercises validated these elementary lesions<sup>30</sup>.

*Large vessel vasculitis/giant cell arteritis (GCA).* The US appearance of normal temporal and extracranial large arteries (e.g., axillary arteries) and of respective lesions in vasculitis was defined<sup>31</sup> (Table 2; Supplementary Table 7, available with the online version of this article). As a result of the

consensus exercises, the “halo sign” and the “compression sign” are regarded as the most important US abnormalities for GCA<sup>32</sup>.

## DISCUSSION

US is a unique OMI for rheumatic disease processes because it is capable of identifying both the inflammatory state and the structural damage. Starting from the 2005 preliminary definitions, novel US definitions have been developed and validated by the WG. In accordance with the Filter 3.1, the validation process of an US definition follows a stringent, step-by-step road map beginning with an SLR following the OMERACT Framework Instrument Selection Algorithm recommendations. Next is a Delphi consensus process, and image- and patient-based reliability studies<sup>33</sup>. For proof, responsiveness studies of US definition of synovitis and tenosynovitis have been carried out<sup>8,15</sup>. Along with progressive implementation of the OMI into clinical trials, patient feedback will enforce refinement of the application of US, which is in agreement with the current Filter 2.1.

The WG work is far from done. Goals now include validating US as an OMI for monitoring disease activity in Sjögren syndrome, musculoskeletal involvement of SLE, dactylitis in PsA (which remains one of the most challenging concepts to reliably identify by imaging), cartilage involvement in RA, and scleroderma. As for dactylitis, work continues on a definition of paratendinitis.

In addition to the development and validation of new US definitions of different pathologies, further research needs to delineate the (minimal) discriminatory threshold of these US pathologies. The first attempt will be to define the threshold of an active synovitis in RA. Another important future

Table 2. New definitions of the elementary lesions composing the US pathologies.

Pathology	Inflammatory Elementary Lesion	Structural Elementary Lesion
Synovitis	Synovial hypertrophy is defined as the presence of abnormal hypoechoic synovial tissue within the capsule that is not displaceable and poorly compressible and that may exhibit Doppler signals	
Enthesitis	Hypoechoic increased thickness of anatomical enthesis (i.e., tendon insertion < 2 mm from the bony surface) that exhibits Doppler signal	Calcifications/enthesophytes at enthesis, erosions at enthesis
Tenosynovitis	Tenosynovial hypertrophy is defined as the presence of abnormal hypoechoic (relative to tendon fibers) tissue within the synovial sheath that is not displaceable and poorly compressible, and seen in 2 perpendicular planes; it may exhibit Doppler signals	
OA osteophytes		Step-up bony prominence at the bony margin that is visible in 2 perpendicular planes
OA hyaline cartilage damage		Loss of anechoic structure and/or thinning of cartilage layer, and irregularities and/or sharpness of at least 1 cartilage margin
Gout DC		Abnormal hyperechoic band over the superficial margin of the articular hyaline cartilage, independent of the angle of insonation which may be either irregular or regular, continuous or intermittent and can be distinguished from the cartilage interface sign
Gout tophus		Circumscribed, inhomogeneous, hyperechoic and/or hypoechoic aggregation (which may or may not generate posterior acoustic shadow), which may be surrounded by a small anechoic rim
Gout aggregates		Heterogeneous hyperechoic foci that maintain their high degree of reflectivity, even when the gain setting is minimized or the insonation angle is changed and which occasionally may generate posterior acoustic shadow
CPPD fibrocartilage		Hyperechoic deposits of variable shape, localized within the fibrocartilage structure, that remain fixed or move along with the fibrocartilage during dynamic assessment
CPPD hyaline cartilage		Hyperechoic deposits of variable size and shape, without posterior shadowing, localized within the hyaline cartilage, that remain fixed and move along with the hyaline cartilage during dynamic assessment
CPPD tendon		Hyperechoic, linear structure(s) generally without posterior shadowing, localized within the tendon and remaining fixed and moving along with the tendon during dynamic assessment
CPPD synovial fluid		Hyperechoic deposits of variable size, localized within the synovial fluid, without posterior shadowing, and mobile along with joint movement and probe pressure
Halo sign	Homogeneous, hypoechoic wall thickening, well delineated toward the luminal side, visible in 2 perpendicular planes, most commonly concentric in transverse scan	
Compression sign	Thickened arterial wall remains visible under compression, i.e., the echogenicity contrasts hypoechoic because of vasculitic vessel wall thickening in comparison to mid/hyperechoic surrounding tissue	

US: ultrasound; DC: double contour; OA: osteoarthritis; CPPD: calcium pyrophosphate deposit.

activity will be the development of a reduced joint count based on the existing EULAR-OMERACT scoring system.

We have redefined OMERACT definitions of US pathologies and elementary lesions. These updated definitions provided clarity as we completed the validation of these criteria and scoring systems, which are now proposed for approval for application in clinical trials.

## APPENDIX 1.

List of study collaborators. The OMERACT Ultrasound Working Group: Sibel Aydin, Marina Backhaus, Artur Bacht, Isabelle Chary-Valckenaere, Stavros Chrysidis, Nemanja Damjanov, Bhaskar Dasgupta, Emilio Filippucci, Frederique Gandjbachkh, Andrew Filer, Stephanie Finzel, Petra Hanova, Alojzija Hocevar, Cristina Hernandez Diaz, Kei Ikeda, Nevsun Inanc, Gurjit Kaeley, Marion Kortekaas, Gavin Lee, Damien Loeuille, Silvia Magni Manzoni, Clara Malattia, Mihaela Micu, Ingrid Moller, Carlos



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## ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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