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Title: International multispecialty consensus on how to image, define, and grade ultrasound imaging features of first metatarsophalangeal joint osteoarthritis, a Delphi consensus study

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Abstract

Objective

To reach consensus concerning which ultrasound imaging features should be assessed and graded, and what ultrasound imaging procedure should be performed when examining osteoarthritic change in the first metatarsophalangeal joint.

Design

An online Delphi study was conducted over four iterative rounds with 16 expert health professionals. Items were scored from 0-100 (0 = not at all important; 100 = extremely important). Consensus was defined based upon an item receiving a median score of $\geq 70\%$ acceptance. Items receiving median score of $\leq 50\%$ were rejected. Items considered ambiguous (median score 51% - 69% of acceptance) were assessed in an additional round. A final round determined the content validity of items through calculation of the content validity ratio and content validity index.

Results

Sixteen items were deemed essential, which included osteophytes graded dichotomously, cartilage damage graded continuously, synovitis and joint space narrowing graded on a semiquantitative scale. The panel deemed essential that the first metatarsophalangeal joint start in a neutral position, then move through range of motion for both dorsal and plantar scanning, orientating the probe in longitudinal and in transverse, whilst using first metatarsal head and proximal phalanx as anatomical landmarks. A supine body position was only deemed essential for a dorsal scan and a neutral foot/ankle position was only rated essential for a plantar scan. The content validity index of the 16 essential items was 0.19.

Conclusion

54 The consensus exercise has identified the essential components the ultrasound imaging
55 acquisition procedure should encompass when examining first metatarsophalangeal joint
56 osteoarthritis.

57

58

59 **Keywords**

60 Osteoarthritis

61 Metatarsophalangeal Joint

62 Ultrasound imaging

63 Foot

1 Introduction

2 Osteoarthritis (OA) is a global health burden and leading cause of chronic pain, joint
3 stiffness, functional limitation, and disability among older adults ^{1,2}. Within the foot, the first
4 metatarsophalangeal joint (MTPJ) is the most commonly affected joint with a prevalence of
5 8% for individuals aged over 50 years ³. By age 60 years, radiographic first MTPJ OA is
6 present in approximately 46% of women and 32% of men ⁴.

7
8 There has been a fundamental shift in our understanding of OA, from a cartilage-only
9 disease to a whole organ disease, recognising the heterogeneous involvement of multiple
10 joint tissues, including cartilage damage, subchondral bone remodelling, synovial
11 inflammation, and osteophyte development ⁵⁻⁷. OA is not simply a process of wear and tear,
12 but rather abnormal remodelling of joint tissues driven by a host of inflammatory mediators ⁷,
13 ⁸. Attention has now turned to the prognostic value and role of inflammatory markers ⁷⁻⁹, with
14 several studies reporting an association between active synovitis and structural OA
15 progression ¹⁰⁻¹². Despite this advancement in knowledge our current method of diagnosing
16 foot OA is governed by the findings of conventional radiography ^{13, 14}, which captures OA
17 later in the disease process when irreversible structural damage has already occurred.

18
19 Ultrasound (US) imaging potentially affords inherent advantages for the diagnosis of first
20 MTPJ OA, providing a whole organ assessment with multiplanar acquisitions, enabling a
21 more detailed assessment of pathology ^{15, 16}. US has gained recognition due to its ability to
22 detect inflammatory joint pathology that is otherwise not detected by clinical examination ^{5, 17},
23 and reliably quantify both bone and soft-tissue abnormalities ¹⁵. Given the ability of US to
24 depict tissue-specific morphological changes before the onset of pain and before the point of
25 irreversible structural damage, US may play a fundamental role in the earlier detection and
26 assessment of foot OA ^{18, 19}, thus enabling more targeted and timely interventions that may

provide capacity to alter disease progression. However, the role of US imaging for OA diagnosis in foot joints has not been clearly defined.

Currently, the use of US to categorise OA-related joint changes has several limitations: Firstly, it is not known what US features are specific to and representative of first MTPJ OA. Secondly, there is no clear consensus as to which type of grading system (e.g. dichotomous or on a semiquantitative scale) should be applied to determine degree of severity for each US feature. Finally, it is unclear what US imaging acquisition procedure should be used to examine the first MTPJ. Therefore, the objective of this research was to adopt a Delphi study design to reach consensus concerning US imaging of first MTPJ OA.

Methods

Design

An online four-round Delphi study design was undertaken to achieve consensus on which US features are indicative of first MTPJ OA, how features should be graded, and what US imaging acquisition procedure is preferable when examining the first MTPJ. The Delphi method is an iterative series of structured rounds that surveys experts to achieve a convergence of opinion in order to gain group consensus²⁰. Subsequent survey rounds refine and define the items, gauging their accuracy or support from the participants²¹. This method is considered an appropriate means of dealing with an absence of guidelines²⁰. Conducting and REporting of DElphi Studies (CREDES) recommendations were adopted to provide guidance on a reporting standard²². Details of how our study reporting aligned with the CREDES recommendations are detailed in Supplementary Data 1. The study was approved by *Auckland University of Technology Ethics Committee (AUTEC) (21/117)*.

Participants

Study recruitment occurred via one of two pathways: (1) potential participants were recruited via their association with the Osteoarthritis Research Society International (OARSI) Foot and Ankle OA discussion group, the United Kingdom (UK) Podiatry US group or the European League Against Rheumatism (EULAR) US network group. The three network groups consist of expert health professionals from either a clinical and/or academic background: rheumatologists, sonographers, radiologists, podiatrists, physiotherapists, epidemiologist, academics, researchers, and orthopaedic surgeons. Geographically, members were located in New Zealand, Australia, United Kingdom, United States of America, Canada, Spain, Brazil, Italy, Netherlands, and Japan. Therefore, the three groups were diverse, and a representative group of clinicians and researchers involved in the investigation of foot and ankle OA ²³. Alternatively, (2) participants were identified through snowball sampling, in which potential participants were invited to participate through a known contact of the primary researcher (PM). All participants were anonymised to each other, enabling them to share their own thoughts without judgement ²⁴.

Survey format

The Delphi survey was implemented using online survey platform Qualtrics® (Qualtrics Research Suite Provo. UT 2013). Each round of the Delphi was piloted among co-authors (MC, CB, RE and KR) who were not participants, to refine the format and question design. Participants were requested to consider each question in terms of developing an US atlas to grade the degree of osteoarthritic related change in the first MTPJ. Consent was obtained prior to the commencement of each round and there was no intra-panel communication. Participants were given a four-week deadline to complete each Delphi round. Reminders were sent via email two weeks following the opening of each round, and participants were given an additional two weeks to complete the round before being classified as a non-responder. After the deadline, the surveys were collated.

Procedure

Delphi Round 1

The Delphi was developed using an evidence driven approach with findings from a systematic review ²⁵ and scoping review ²⁶ used to inform Round 1 open-ended questions. The systematic review investigated what US features are associated with OA in peripheral joints and how US features in peripheral joints are defined and graded ²⁵. The scoping review investigated US imaging acquisition procedures and guidelines used to assess the first MTPJ ²⁶. Round 1 included participant information, online consent, instructions, and the Round 1 survey (Supplementary Data 1). Round 1 was divided into two sections: (i) participant characteristic questions and (ii) open-ended questions concerning US imaging of first MTPJ OA. Due to the inconsistencies reported in both reviews and the dearth of knowledge specific to first MTPJ OA, open-ended questions were specifically aimed to encourage alternative views to determine which US features are indicative of first MTPJ OA, how should those features be graded, and what US imaging acquisition procedure should be used to evaluate the first MTPJ.

Survey responses were exported and analysed in Microsoft® Excel®, version 2205 with responses collated into the following sections: Part A: First MTPJ OA US features; Part B: Grading US features and Part C: US imaging acquisition procedure. The US imaging acquisition procedure was further broken down into two components (I) Patient body and lower limb positioning (dorsal and plantar) and (II) Probe position (longitudinal and transverse). Data were presented as medians and interquartile range unless otherwise noted.

All Round 1 responses were collated with similar responses amalgamated to ensure that the subsequent round was not repetitive and easy to complete. A set of themes were established that mapped US features, grading systems and US imaging acquisition procedure; to create items for Round 2 ²⁷. Themes were developed through qualitative

descriptive analysis^{28, 29} and reviewed by a second author (MC). Open-ended responses from Round 1 were combined with additional items generated from the systematic and scoping reviews^{25, 26}, that were not identified by participants in Round 1.

Delphi Round 2

Due to reduced uptake of Round 1, linked to timing in the midst of the COVID pandemic, Round 2 was redistributed to all three network groups, via pathway one and to those that were invited to participate through snowballing method. Potential participants were sent an invitation email containing the Round 2 survey link. Participants were required to rate their level of agreement for each item using a sliding scale from 0-100 (0 = not at all important; 100 = extremely important). The Round 2 survey is detailed in Supplementary Data 2. Consensus was defined based upon items receiving a median score of $\geq 70\%$ of acceptance³⁰. Items receiving a median score of $\leq 50\%$ were rejected. Items where there was disagreement, were considered as being ambiguous (answers receiving a median score between 51% - 69% of acceptance) and were taken back to participants for further consideration in Round 3²¹.

Delphi Round 3

An invitation to participate in Round 3 was only sent to those participants who responded to Round 2. In Round 3, participants were asked to accept or reject ambiguous items generated in Round 2 (answers receiving a median score of between 51% - 69% of acceptance). Round 3 provided participants the opportunity to change their answers considering the group's median. To aid in consensus decision making, participants were provided the results from Round 2, which included the group median score and interquartile range (IQR). For Round 3, consensus was defined based upon item statements receiving a median score of $\geq 70\%$ of acceptance. Statements receiving a median score of $< 70\%$ were rejected^{30, 31}. The Round 3 survey is outlined in Supplementary Data 3.

Delphi Round 4: Content validity

Evaluating content validity is a critical step in the development process, which demonstrates the final items are representative of the entire domain the assessment seeks to measure³², thus ensuring the US atlas contains the appropriate content to diagnose and grade first MTPJ OA. To determine the content validity of items to be included in the atlas, all participants who participated in Round 3 were asked to rate all accepted items into one of three categories: “essential,” “useful, but not essential,” or “not necessary.” The Round 4 survey is detailed in Supplementary Data 4. The content validity ratio (CVR) was used to determine the content validity of each item included in Round 4, using the formula proposed by Lawshe³³. The CVR is a widely applied statistic when quantifying content validity of instruments which involves a panel of 'experts'³². Items perceived as "essential" by $\geq 50\%$ of the panel members, provides assurance of content validity³³. A positive CVR indicates more than 50% of the panel members rate the item as essential. Items deemed not essential by $\geq 50\%$ of panel members were discarded. The content validity index (CVI) was calculated. The CVI is the mean of the CVR values of the retained items and is an indicator of overall content validity^{32, 33}.

Results

Participant characteristics

Round 1 of the Delphi exercise received 10 responses. Table 1 details the characteristics of the 10 participants who completed Round 1. Round 2 received 20 responses. Sixteen participants completed Round 3, of which all 16 participants completed Round 4 (content validity round). Although the invited participants varied with regard to demographics and experience, the respondents were researchers, podiatrists, physiotherapists, sonographers, radiographers and a physiatrist. The characteristics of the 16 participants who completed Rounds 2, 3 and 4 are detailed in Table 2. Participants were predominantly female (6 male:

10 female), aged over 40 years old (81%), White British ethnicity (44%) and currently living in the UK (50%). Participants were predominantly podiatrists and/or researchers (44%). Two thirds of the participants reported to have between 0-10 years of musculoskeletal US experience. Half the participants reported they held no formal qualification relating to musculoskeletal US.

Insert Table 1 near here.

Insert Table 2 near here.

Delphi findings

Figure 1 details the number of participants involved in each round and the number of items developed, accepted, and/or rejected from each round. Authors identified 50 open-ended items based on the participants free-text responses in Round 1. These items were combined with an additional 12 items generated from the authors' recent systematic²⁵ and scoping reviews²⁶ to be considered in Round 2. Participants rated 62 items in Round 2, 23 items reached consensus (medians score of $\geq 70\%$), 21 items were considered ambiguous (achieved a median score between 51–69% agreement), and 18 items were excluded (median score $\leq 50\%$). As a result of two features (tenosynovitis and capsulitis) being excluded their associated grading systems, which were rated as ambiguous were also excluded. In Round 3, participants rated the 21 ambiguous items, three items achieved $\geq 70\%$ agreement and 18 items were excluded. Of the 18 items that were excluded, three were features (synovial hypertrophy, joint effusion and joint erosion) that had previously accepted grading systems from Round 2. For that reason, their associated grading system were now excluded. All accepted items and the round they were accepted are displayed in Table 3. Subsequently, 23 accepted items were included in the content validity round (Round 4). Sixteen items were deemed essential by $\geq 50\%$ of the participants with a CVI of 0.19 (Table 4).

Insert Figure 1 near here.

Insert Table 3 near here.

Insert Table 4 near here.

Discussion

The Delphi study design sought to generate consensus between experts to inform the methodological development of an US atlas to grade the degree of osteoarthritic related change in the first MTPJ. Through applying a Delphi study design, the panel rated 16 items as 'essential' across three domains: first MTPJ OA US features, grading US features, and US imaging acquisition procedure.

OA is characterised by both structural damage and inflammatory abnormalities³⁴. Four US features rated as essential to be included in the US atlas were synovitis, osteophytes, joint space narrowing, and cartilage damage/thickness. It is well understood that inflammation is an important driver of the disease and contributes to the pain experienced and the structural progression of the disease¹⁰⁻¹². Given the prognostic value of inflammatory features and the sensitivity US possesses in detecting subclinical inflammatory change^{5, 17}, the inclusion of multiple inflammatory features may be more helpful in elucidating the role of inflammation in foot OA. In contrast, a recent US consensus-based study, conducted by Outcome Measures in Rheumatology (OMERACT), for grading hand OA³⁵, scored greyscale inflammatory abnormalities for synovial hypertrophy and joint effusion separately in addition to power Doppler signal (flow signal detected within synovial hypertrophy to be considered a sign of synovitis)^{35, 36}. Furthermore, the OMERACT hand OA study reported marked variation in prevalence between greyscale and Doppler detected inflammatory features³⁵. Greyscale inflammatory features, joint effusion and synovial hypertrophy were frequently observed (40% and 45% respectively). In contrast power doppler signals (considered a sign of

synovitis) were reported in 6% of interphalangeal joints ³⁵. Therefore, the exclusion of greyscale features indicative of inflammation may result in OA being underestimated.

The inclusion of synovitis as the only marker of inflammation may be reflective of the inconsistencies in the different entities of synovial pathology indicative of inflammation ²⁵. There has been marked variations across studies in terms of how synovitis, synovial hypertrophy and joint effusion are defined and categorised as US features ²⁵. The inclusion of synovitis as a core element for the US evaluation of first MTPJ OA aligns with a preliminary US grading system for hand OA, that combined synovial hypertrophy and joint effusion into one greyscale synovitis score ³⁷. Whilst the recent OMERACT definition encompasses the whole concept of synovitis being the “presence of a hypoechoic synovial hypertrophy regardless of the presence of effusion or any grade of Doppler signal” ³⁸, it does necessitate the inclusion of Doppler signal as part of image acquisition when examining synovitis.

To date, one of the most notable imaging advancements specific to foot OA was the development of the La Trobe Radiographic Foot Atlas in 2007 ¹³. This atlas incorporates both osteophytes and joint space narrowing to provide a quantitative means of assessing foot OA. For that reason, the acceptance of both structural features (osteophytes and joint space narrowing) may have been influenced by their role in the radiographic foot atlas ¹³. Regardless, US imaging has been shown to detect more joints with osteophytes than conventional radiography ^{39, 40}. The inclusion of osteophytes and joint space narrowing will allow for comparison between radiographic and sonographic detection and grading, consequently enabling the construct validity between imaging modalities to be determined.

Although the heterogeneous involvement of multiple joint tissues is now well recognised, cartilage damage remains the cornerstone in the pathophysiology of OA⁴¹, this was reflected by its acceptance as an essential US feature. Unlike radiography, US can directly visualise some parts of articular cartilage⁴². Cartilage damage may not be uniform across the entire joint^{43, 44}. Therefore, the ability to consistently examine the exact same part of cartilage, with US, will influence the reliability and validity of this measure. Given the general opinion that US imaging is heavily operator dependent for image acquisition and interpretation^{45, 46}, investigating the reliability of grading cartilage damage would be critical before inclusion into the US atlas. This reinforces the need for further refinement of anatomical landmarks to guide probe positioning to ensure a standardised US imaging acquisition procedure.

Current US grading systems applied to OA have been largely extrapolated from those originally designed and validated to quantify inflammatory change in rheumatoid arthritis (RA)²⁵. Inflammation associated with OA is fundamentally different from that in RA, with OA having lower levels of inflammatory proteins⁴⁷, less pronounced synovitis^{48, 49}, no response to biologic drugs used in RA, and mediated primarily by the innate immune system⁸. The distinct difference of inflammation experienced in OA compared to RA^{11, 50}, reinforces the need for OA-specific grading systems that truly depict the disease progression of first MTPJ OA.

Both dichotomous and semiquantitative grading systems were accepted for osteophytes. However, a dichotomous grading system was deemed essential by the panel members. While dichotomous scoring may be viewed as a simpler method to distinguish between the absence or presence of a feature, it presents no mechanism to determine the progression of first MTPJ OA over time. Alternatively, a semiquantitative grading system was accepted for

synovitis and joint space narrowing. A semiquantitative system enables quantification of disease progression and provides insight into the degree of osteoarthritic change²⁵. Issues related to the subjectivity of semiquantitative systems have been highlighted, with challenges in interpretation and differentiation between grading of disease severity⁵⁰. This may be reflective of the lack of consensus to guide grading and/or studies which have extrapolated RA grading systems to OA. The acceptance of cartilage damage/thickness to be graded using a continuous measure will mitigate issues with distinguishing between grades of severity.

An US imaging acquisition procedure involves numerous variables that need to be considered as part of examination, these include patient positioning, transducer orientation and surfaces scanned. As it stands only two consensus-based guidelines exist to inform the US imaging acquisition procedure to assess the first MTPJ^{16, 51}. Despite this, there has been marked inconsistency in the application of guidelines across studies²⁶. The 2001 EULAR guidelines included limited instructions on body position, transducer orientation and surfaces of the first MTPJ to scan (supine position for the dorsal scans and prone position for the plantar scans)⁵¹. In 2017 a new EULAR-endorsed task force revised the standardised procedures for US imaging in rheumatology¹⁶. The updated EULAR guidelines for performing US imaging of the first MTPJ addressed patient positioning, transducer orientation, probe position (starting point) and, scanning technique¹⁶. Despite this enhancement, the revised guidelines still lack sufficient detail outlining specific anatomical reference points to ensure a standardised US imaging acquisition procedure.

The Delphi panel considered both patient and lower limb positioning for scanning the dorsal, plantar and medial surface of the first MTPJ. Although accepted, scanning the medial aspect of the first metatarsal head and proximal phalanx, was not rated as an essential item. Eight

items were deemed essential when scanning both dorsal and plantar surfaces of the first MTPJ. Unlike previous guidelines, the Delphi panel included first MTPJ positioning. Wherein it was deemed essential that the first MTPJ should start in a neutral position (the position where the foot is neither pronated nor supinated), then move through full range of motion during the scanning procedure for both a dorsal and plantar scans. Consistent with both 2001⁵¹ and 2017 guidelines¹⁶, a supine body position was deemed essential, however only when performing a dorsal scan. Positioning the ankle/foot in neutral was deemed essential, although only for a plantar scan. This is inconsistent with the 2017 guidelines which reported a dorsiflexed foot position¹⁶. The 2001 guideline⁵¹ provided no further detail on how the lower limb should be positioned. Regarding knee positioning, a flexed and extended knee were accepted items for both dorsal and plantar scans respectively. Both knee positions are consistent with the 2017 guidelines¹⁶, however neither item were rated as essential.

The Delphi panel also deemed essential that the probe be orientated both longitudinally and transverse when scanning the dorsal and plantar aspect of the first MTPJ. Specifically, for a longitudinal scan the probe should be positioned on the plantar/dorsal aspect of the forefoot, parallel to the first metatarsal head and proximal phalanx, joint line central to the image. In conjunction with a transverse scan, where the probe should be positioned on the plantar/dorsal aspect of the foot, perpendicular to the diaphysis of the first metatarsal then move distally to the diaphysis of first proximal phalanx, joint line central to the image. Previous guidelines provide limited descriptions of anatomical landmarks to guide probe positioning. The revised 2017 guidelines only reported performing a transverse scan when examining articular cartilage¹⁶. The findings of the Delphi support the application of a multiplanar technique when examining the first MTPJ. A multiplanar technique is crucial in cases where one feature (e.g. joint effusion or osteophyte) is obstructing the view of another feature under examination, or when there is severe structural changes, often associated with rheumatic diseases.

317

318 A strength of the current study was the inclusion of content validity. Evaluating content
319 validity is a critical step in the development process of instruments used to measure
320 constructs in research ³². Content validity provides evidence to the extent at which items of
321 an assessment instrument are representative of the entire domain the assessment seeks to
322 measure ³². Our findings need to be viewed in the context of several limitations. Firstly, the
323 exercise was primarily dependent upon an expert consensus based approach ⁵². Therefore,
324 it needs to be acknowledged that it is based on the subjective opinion of the participants,
325 which in the context of evidence-based practice constitutes low level evidence ⁵³. Secondly,
326 the low sample obtained, and level of professional experience may have limited the potential
327 for ideas as well as the number of generated items. The low number of participants maybe
328 reflective of participant recruitment proceeding during the midst of the COVID-19 pandemic.
329 Thirdly, author bias may have been introduced during the amalgamation of Delphi items.
330 However, the authors have attempted to minimise this with transparency of the implemented
331 process. Fourthly, anonymity and confidentiality are suggested requirements of participants
332 in Delphi surveys to minimise the effects, if any, of collusion ²⁰. It cannot be guaranteed that
333 participants remained anonymous to their colleagues, however there was no instance where
334 the authors believed anonymity was not maintained. All participants were asked to keep both
335 their responses and participation confidential to minimise this bias risk. Finally, the term
336 'expert' and its application to health practitioners is controversial ²⁴. By inviting members
337 from three different groups (OARSI, UK Podiatry US, and EULAR US network), it is
338 expected that the relevant knowledge, experience, and diversity was reflected in the expert
339 panel members.

340

341 **Implications for further research**

The outcomes of the Delphi study will inform future studies into the methodological development of an US atlas to grade the degree of osteoarthritic change in the first MTPJ. Ongoing research is crucial in determining the capacity of US to detect early inflammatory changes that precede osseous involvement, therefore informing more timely management approaches that aim to prevent further structural progression.

Conclusion

Sixteen items were accepted as essential for the US examination of first MTPJ OA. This included osteophytes graded dichotomously, cartilage damage graded on a continuous scale, synovitis and joint space narrowing graded on a semiquantitative scale. The first MTPJ imaged in both dorsal and plantar orientation with the body supine for a dorsal scan and a neutral ankle position for a plantar scan. This data will be the catalyst in developing a US classification criterion, specific for first MTPJ OA.

List of Abbreviations

Osteoarthritis: OA
Metatarsophalangeal Joint: MTPJ
Ultrasound: US
Osteoarthritis Research Society International: OARSI
United Kingdom: UK
European League Against Rheumatism: EULAR
Content Validity Ratio: CVR

364 Content Validity Index: CVI

365 Outcome Measures in Rheumatology: OMERACT

366 Rheumatoid Arthritis: RA

367

368 **Declarations**

369 **Ethical approval and consent to participate**

370 The study was approved by Auckland University of Technology Ethics Committee (AUTEC)
371 (21/117).

372

373 **Consent for publication**

374 Not applicable

375

376 **Competing interests**

377 All authors declare they have no competing interests.

378

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382 analysis, or interpretation of the data, or in the decision to submit the article for publication.

383

384 **Authors' contributions**

All authors (PM, CB, RE, KR and MC) were responsible for the conception and design of the research. PM was responsible for the initial development of the survey, with all authors providing critical review of each round. Analysis and management of the data were undertaken by PM and MC. PM, CB, RE, KR and MC were responsible for the preparation and review of the manuscript prior to submission for publication. PM, CB, RE, KR and MC read and approved the final manuscript.

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Availability of data and materials

All available data is provided within the manuscript

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Table 1 Demographics of participants who completed Round 1

| | | n (%) |
|--|---|--------------|
| Gender | Male | 4 (40) |
| | Female | 6 (60) |
| Age range | 20-29 years old | 1 (10) |
| | 30-39 years old | 1 (10) |
| | 40-49 years old | 5 (50) |
| | 50-59 years old | 2 (20) |
| | Over 60 years old | 1 (10) |
| Ethnicity | Caucasian | 1 (10) |
| | Hispanic | 1 (10) |
| | NZ European | 1 (10) |
| | White British | 7 (70) |
| Country | Australia | 1 (10) |
| | New Zealand | 1 (10) |
| | Spain | 1 (10) |
| | United Kingdom | 7 (70) |
| Profession | Physiotherapist | 1 (8.3) |
| | Podiatrist | 6 (50) |
| | Sonographer | 1 (8.3) |
| | Radiographer | 1 (8.3) |
| | Researcher | 3 (25) |
| Clinical or Academic | Clinical | 1 (10) |
| | Academic | 3 (30) |
| | Both Clinical: Academic | 6 (60) |
| MSK USI experience (years) | 0-5 years | 4 (40) |
| | 6-10 years | 3 (30) |
| | 11-15 years | 2 (20) |
| | Over 20 years | 1 (10) |
| Highest qualification relating to MSK USI | MSc Medical Ultrasound | 2 (20) |
| | PGDip Medical Ultrasound | 1 (10) |
| | PGCert Medical Ultrasound | 2 (20) |
| | Continued Professional Development course | 1 (10) |
| | No formal USI qualifications | 4 (40) |

*Some participants selected more than one academic and/or professional background

Table 2 Demographics of participants who completed Round 4

| | | n (%) |
|--|---|--------------|
| Gender | Male | 6 (38) |
| | Female | 10 (62) |
| Age range | Under 20 years old | 0 (0) |
| | 20-29 years old | 2 (13) |
| | 30-39 years old | 1 (6) |
| | 40-49 years old | 6 (40) |
| | 50-59 years old | 3 (19) |
| | Over 60 years old | 4 (25) |
| Ethnicity | Caucasian | 3 (19) |
| | Hispanic | 1 (6) |
| | Irish | 1 (6) |
| | Italian | 1 (6) |
| | NZ European | 1 (6) |
| | White British | 7 (44) |
| | White | 2 (13) |
| Country | Australia | 2 (14) |
| | Canada | 1 (6) |
| | Italy | 1 (6) |
| | Netherlands | 1 (6) |
| | New Zealand | 1 (6) |
| | Spain | 1 (6) |
| | United Kingdom | 8 (50) |
| | United States of America | 1 (6) |
| Profession | Physiatrist | 1 (6) |
| | Physiotherapist | 3 (19) |
| | Podiatrist | 7 (44) |
| | Sonographer | 1 (6) |
| | Radiographer | 1 (6) |
| | Researcher | 7 (44) |
| Clinical or Academic | Clinical | 2 (12) |
| | Academic | 6 (38) |
| | Both Clinical: Academic | 8 (50) |
| MSK USI experience (years) | 0-5 years | 7 (44) |
| | 6-10 years | 4 (24) |
| | 11-15 years | 2 (13) |
| | 16-20 years | 2 (13) |
| | Over 20 years | 1 (6) |
| Highest qualification relating to MSK USI | MSc Medical Ultrasound | 2 (13) |
| | PGDip Medical Ultrasound | 1 (6) |
| | PGCert Medical Ultrasound | 4 (25) |
| | Continued Professional Development course | 1 (6) |
| | No formal USI qualifications | 8 (50) |

*Some participants selected more than one academic and/or professional background

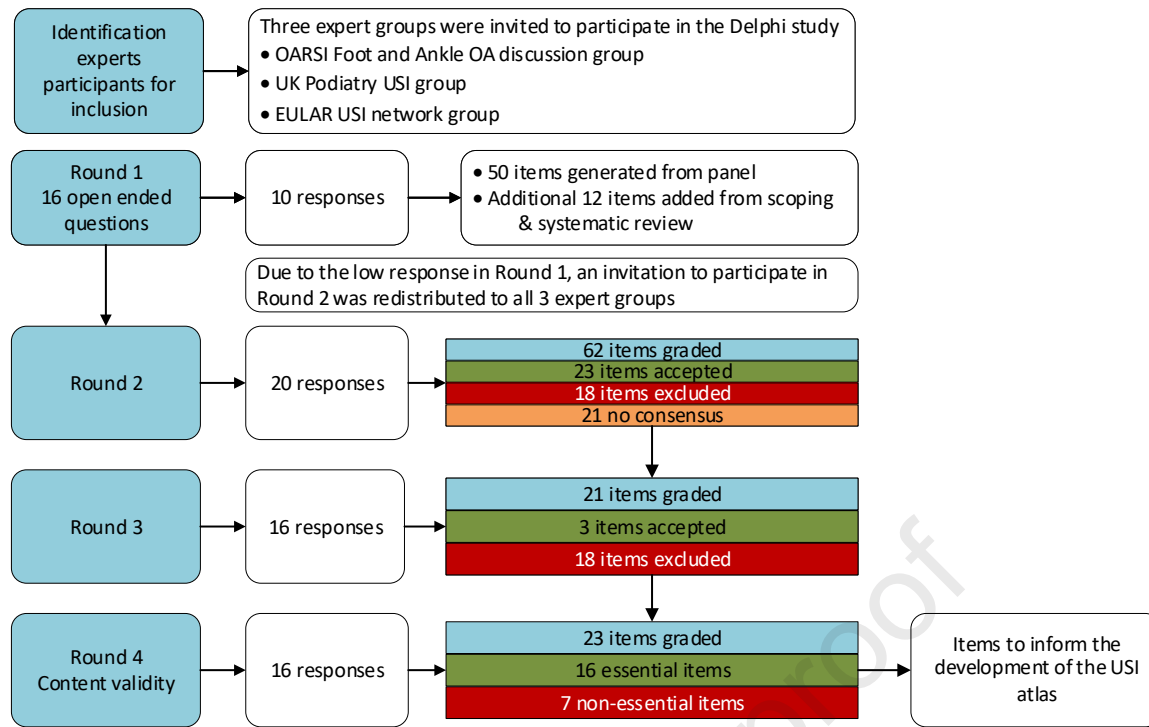
Table 3 All accepted items from the Delphi survey used to inform the methodological development of an US atlas to grade the degree of osteoarthritic change in the first MTPJ.

| Item category | Item (round accepted) | Percentage score median (IQR) |
|---|---|-------------------------------|
| PART A: First MTPJ OA ultrasound imaging features | Synovitis (2) | 70 (42-80) |
| | Osteophytes (2) | 81 (65-100) |
| | Cartilage damage (2) | 89 (73-94) |
| | Joint space narrowing (2) | 79 (71-93) |
| PART B: Grading ultrasound imaging features | Synovitis Semiquantitative (3) | 74 (55-80) |
| | Osteophytes Dichotomous (2) | 78 (29-84) |
| | Osteophytes Semiquantitative (3) | 70 (51-80) |
| | Cartilage damage/thickness Cont (mm) (2) | 78 (35-84) |
| | Joint space narrowing Semiquantitative (3) | 75 (63-80) |
| PART C: US Imaging acquisition protocol Patient positioning (Dorsal) | Body position – Supine (2) | 86 (73-90) |
| | Knee position – Flexed (2) | 82 (27-87) |
| | Ankle/foot position – neutral (2) | 75 (58-91) |
| | Ankle/foot position - Foot flat on plinth (2) | 72 (46-84) |
| | First MTPJ position -Start in neutral then move through ROM during scanning (2) | 84 (67-90) |
| Patient positioning (Plantar) | Knee position - extended | 74 (60-92) |
| | Ankle/foot position – neutral (2) | 80 (69-82) |
| | First MTPJ position -Start in neutral then move through ROM during scanning (2) | 79 (66-87) |
| Probe position (Longitudinal) | Dorsal aspect of the forefoot, parallel to the first metatarsal head and proximal phalanx, joint line central to the image (2) | 79 (75-90) |
| | Plantar aspect of the forefoot, parallel to the first metatarsal head and proximal phalanx, joint line central to the image (2) | 76 (67-80) |
| | Medial aspect of metatarsal head and proximal phalanx, joint line central to the image (2) | 79 (78-87) |
| Probe position (Transverse) | Dorsal aspect of the foot, perpendicular to diaphysis of the first metatarsal then move distally to the diaphysis of first proximal phalanx, joint line central to the image (2) | 82 (78-92) |
| | Plantar aspect of the foot, perpendicular to diaphysis of the first metatarsal then move distally to the diaphysis of first proximal phalanx, joint line central to the image (2) | 77 (56-90) |
| | Medial aspect of metatarsal head and proximal phalanx, joint line central to the image (2) | 72 (60-76) |

Table 4 The content validity ratio (CVR) of each item included in Round 4

| Round 4 items | CVR Value | |
|---|-----------|-------|
| PART A: FIRST MTPJ OA ULTRASOUND IMAGING FEATURES | | |
| Synovitis | 0 | |
| Osteophytes | 0.25 | |
| Cartilage damage | 0.13 | |
| Joint space narrowing | 0.5 | |
| PART B: GRADING ULTRASOUND IMAGING FEATURES | | |
| Synovitis Semiquantitative | 0 | |
| Osteophytes Dichotomous | 0.25 | |
| Osteophytes Semiquantitative | | -0.38 |
| Cartilage damage/thickness Cont (mm) | 0 | |
| Joint space narrowing Semiquantitative | 0.5 | |
| PART C: US IMAGING ACQUISITION PROTOCOL (Dorsal) | | |
| Body position - Supine | 0.13 | |
| Knee position - Flexed | | -0.38 |
| Ankle/foot position - neutral | | -0.38 |
| Ankle/foot position - Foot flat on plinth | | -0.13 |
| First MTPJ position -Start in neutral then move through ROM during scanning | 0 | |
| PART C: US IMAGING ACQUISITION PROTOCOL (Plantar) | | |
| Knee position - extended | | -0.13 |
| Ankle/foot position - neutral | 0.13 | |
| First MTPJ position -Start in neutral then move through ROM during scanning | 0.13 | |
| Probe position (Longitudinal) | | |
| Dorsal aspect of the forefoot, parallel to the first metatarsal head and proximal phalanx, joint line central to the image | 0.5 | |
| Plantar aspect of the forefoot, parallel to the first metatarsal head and proximal phalanx, joint line central to the image | 0 | |
| Medial aspect of metatarsal head and proximal phalanx, joint line central to the image | | -0.25 |
| Probe position (Transverse) | | |
| Dorsal aspect of the foot, perpendicular to diaphysis of the first metatarsal then move distally to the diaphysis of first proximal phalanx, joint line central to the image | 0.5 | |
| Plantar aspect of the foot, perpendicular to diaphysis of the first metatarsal then move distally to the diaphysis of first proximal phalanx, joint line central to the image | 0 | |
| Medial aspect of metatarsal head and proximal phalanx, joint line central to the image | | -0.38 |
| CVI | 0.19 | |

Positive values in green shading indicate the items that were deemed essential by $\geq 50\%$ of the participants. Negative values in red shading indicate items that were not deemed essential by $\geq 50\%$ of panel members and were discarded.

**Note**

In Round 3, three features (synovial hypertrophy, joint effusion and joint erosion) were all excluded. However, their grading systems had previously been accepted in Round 2. As a result of the feature being excluded the associated grading systems that had previously been accepted were also now excluded. Accepted items were as follows; 23 (Round 2) + 3 (Round 3) - 3 (grading systems from Round 2).

OSTEOARTHRITIS AND CARTILAGE

AUTHORS' DISCLOSURE

Manuscript title: International multispecialty consensus on how to image, define, and grade ultrasound imaging features of first metatarsophalangeal joint osteoarthritis, a Delphi consensus study

Corresponding author: Prue Molyneux

Authorship

All authors should have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted. By signing below each author also verifies that he (she) confirms that neither this manuscript, nor one with substantially similar content, has been submitted, accepted or published elsewhere (except as an abstract). Each manuscript must be accompanied by a declaration of contributions relating to sections (1), (2) and (3) above. This declaration should also name one or more authors who take responsibility for the integrity of the work as a whole, from inception to finished article. These declarations will be included in the published manuscript.

Acknowledgement of other contributors

All contributors who do not meet the criteria for authorship as defined above should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Such contributors must give their consent to being named. Authors should disclose whether they had any writing assistance and identify the entity that paid for this assistance.

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At the end of the text, under a subheading "Conflict of interest statement" all authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and research grants or other funding.

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All sources of funding should be declared as an acknowledgement at the end of the text.

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Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should state this.

Studies involving humans or animals

Clinical trials or other experimentation on humans must be in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Randomized controlled trials should follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines and be registered in a public trials registry.

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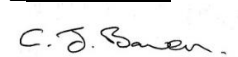
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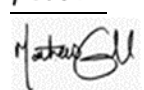
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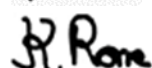
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