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

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28 **Abstract**

29 **Objective**

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

33

34 **Design**

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

42

43 **Results**

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

52

53 **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

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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

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

29

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

37

38 **Methods**

39 **Design**

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

51

52 Participants

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

67

68 Survey format

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

79

80 **Procedure**

81 ***Delphi Round 1***

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

95
96 Survey responses were exported and analysed in Microsoft® Excel®, version 2205 with
97 responses collated into the following sections: Part A: First MTPJ OA US features; Part B:
98 Grading US features and Part C: US imaging acquisition procedure. The US imaging
99 acquisition procedure was further broken down into two components (I) Patient body and
100 lower limb positioning (dorsal and plantar) and (II) Probe position (longitudinal and
101 transverse). Data were presented as medians and interquartile range unless otherwise
102 noted.

103
104 All Round 1 responses were collated with similar responses amalgamated to ensure that the
105 subsequent round was not repetitive and easy to complete. A set of themes were
106 established that mapped US features, grading systems and US imaging acquisition
107 procedure; to create items for Round 2 ²⁷. Themes were developed through qualitative

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

111

112 ***Delphi Round 2***

113 Due to reduced uptake of Round 1, linked to timing in the midst of the COVID pandemic,
114 Round 2 was redistributed to all three network groups, via pathway one and to those that
115 were invited to participate through snowballing method. Potential participants were sent an
116 invitation email containing the Round 2 survey link. Participants were required to rate their
117 level of agreement for each item using a sliding scale from 0-100 (0 = not at all important;
118 100 = extremely important). The Round 2 survey is detailed in Supplementary Data 2.
119 Consensus was defined based upon items receiving a median score of $\geq 70\%$ of acceptance
120 ³⁰. Items receiving a median score of $\leq 50\%$ were rejected. Items where there was
121 disagreement, were considered as being ambiguous (answers receiving a median score
122 between 51% - 69% of acceptance) and were taken back to participants for further
123 consideration in Round 3 ²¹.

124

125 ***Delphi Round 3***

126 An invitation to participate in Round 3 was only sent to those participants who responded to
127 Round 2. In Round 3, participants were asked to accept or reject ambiguous items
128 generated in Round 2 (answers receiving a median score of between 51% - 69% of
129 acceptance). Round 3 provided participants the opportunity to change their answers
130 considering the group's median. To aid in consensus decision making, participants were
131 provided the results from Round 2, which included the group median score and
132 interquartile range (IQR). For Round 3, consensus was defined based upon item statements
133 receiving a median score of $\geq 70\%$ of acceptance. Statements receiving a median score of
134 $< 70\%$ were rejected ^{30, 31}. The Round 3 survey is outlined in Supplementary Data 3.

135

136 **Delphi Round 4: Content validity**

137 Evaluating content validity is a critical step in the development process, which demonstrates
138 the final items are representative of the entire domain the assessment seeks to measure ³²,
139 thus ensuring the US atlas contains the appropriate content to diagnose and grade first
140 MTPJ OA. To determine the content validity of items to be included in the atlas, all
141 participants who participated in Round 3 were asked to rate all accepted items into one of
142 three categories: "essential," "useful, but not essential," or "not necessary." The Round 4
143 survey is detailed in Supplementary Data 4. The content validity ratio (CVR) was used to
144 determine the content validity of each item included in Round 4, using the formula proposed
145 by Lawshe ³³. The CVR is a widely applied statistic when quantifying content validity of
146 instruments which involves a panel of 'experts' ³². Items perceived as "essential" by $\geq 50\%$ of
147 the panel members, provides assurance of content validity³³. A positive CVR indicates more
148 than 50% of the panel members rate the item as essential. Items deemed not essential by
149 $\geq 50\%$ of panel members were discarded. The content validity index (CVI) was calculated.
150 The CVI is the mean of the CVR values of the retained items and is an indicator of overall
151 content validity ^{32, 33}.

152

153 **Results**

154 **Participant characteristics**

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

162 10 female), aged over 40 years old (81%), White British ethnicity (44%) and currently living
163 in the UK (50%). Participants were predominantly podiatrists and/or researchers (44%). Two
164 thirds of the participants reported to have between 0-10 years of musculoskeletal US
165 experience. Half the participants reported they held no formal qualification relating to
166 musculoskeletal US.

167 ***Insert Table 1 near here.***

168 ***Insert Table 2 near here.***

169 **Delphi findings**

170 Figure 1 details the number of participants involved in each round and the number of items
171 developed, accepted, and/or rejected from each round. Authors identified 50 open-ended
172 items based on the participants free-text responses in Round 1. These items were combined
173 with an additional 12 items generated from the authors' recent systematic²⁵ and scoping
174 reviews²⁶ to be considered in Round 2. Participants rated 62 items in Round 2, 23 items
175 reached consensus (medians score of $\geq 70\%$), 21 items were considered ambiguous
176 (achieved a median score between 51–69% agreement), and 18 items were excluded
177 (median score $\leq 50\%$). As a result of two features (tenosynovitis and capsulitis) being
178 excluded their associated grading systems, which were rated as ambiguous were also
179 excluded. In Round 3, participants rated the 21 ambiguous items, three items achieved \geq
180 70% agreement and 18 items were excluded. Of the 18 items that were excluded, three
181 were features (synovial hypertrophy, joint effusion and joint erosion) that had previously
182 accepted grading systems from Round 2. For that reason, their associated grading system
183 were now excluded. All accepted items and the round they were accepted are displayed in
184 Table 3. Subsequently, 23 accepted items were included in the content validity round (Round
185 4). Sixteen items were deemed essential by $\geq 50\%$ of the participants with a CVI of 0.19
186 (Table 4).

187 ***Insert Figure 1 near here.***

188 ***Insert Table 3 near here.***

189 ***Insert Table 4 near here.***

190

191 **Discussion**

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

197

198 OA is characterised by both structural damage and inflammatory abnormalities ³⁴. Four US
199 features rated as essential to be included in the US atlas were synovitis, osteophytes, joint
200 space narrowing, and cartilage damage/thickness. It is well understood that inflammation is
201 an important driver of the disease and contributes to the pain experienced and the structural
202 progression of the disease ¹⁰⁻¹². Given the prognostic value of inflammatory features and the
203 sensitivity US possesses in detecting subclinical inflammatory change ^{5, 17}, the inclusion of
204 multiple inflammatory features may be more helpful in elucidating the role of inflammation in
205 foot OA. In contrast, a recent US consensus-based study, conducted by Outcome Measures
206 in Rheumatology (OMERACT), for grading hand OA ³⁵, scored greyscale inflammatory
207 abnormalities for synovial hypertrophy and joint effusion separately in addition to power
208 Doppler signal (flow signal detected within synovial hypertrophy to be considered a sign of
209 synovitis) ^{35, 36}. Furthermore, the OMERACT hand OA study reported marked variation in
210 prevalence between greyscale and Doppler detected inflammatory features ³⁵. Greyscale
211 inflammatory features, joint effusion and synovial hypertrophy were frequently observed
212 (40% and 45% respectively). In contrast power doppler signals (considered a sign of

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

215

216 The inclusion of synovitis as the only marker of inflammation may be reflective of the
217 inconsistencies in the different entities of synovial pathology indicative of inflammation ²⁵.

218 There has been marked variations across studies in terms of how synovitis, synovial

219 hypertrophy and joint effusion are defined and categorised as US features ²⁵. The inclusion
220 of synovitis as a core element for the US evaluation of first MTPJ OA aligns with a

221 preliminary US grading system for hand OA, that combined synovial hypertrophy and joint

222 effusion into one greyscale synovitis score ³⁷. Whilst the recent OMERACT definition

223 encompasses the whole concept of synovitis being the “presence of a hypoechoic synovial

224 hypertrophy regardless of the presence of effusion or any grade of Doppler signal” ³⁸, it does

225 necessitate the inclusion of Doppler signal as part of image acquisition when examining

226 synovitis.

227

228 To date, one of the most notable imaging advancements specific to foot OA was the

229 development of the La Trobe Radiographic Foot Atlas in 2007 ¹³. This atlas incorporates

230 both osteophytes and joint space narrowing to provide a quantitative means of assessing

231 foot OA. For that reason, the acceptance of both structural features (osteophytes and joint

232 space narrowing) may have been influenced by their role in the radiographic foot atlas ¹³.

233 Regardless, US imaging has been shown to detect more joints with osteophytes than

234 conventional radiography ^{39, 40}. The inclusion of osteophytes and joint space narrowing will

235 allow for comparison between radiographic and sonographic detection and grading,

236 consequently enabling the construct validity between imaging modalities to be determined.

237

238 Although the heterogeneous involvement of multiple joint tissues is now well recognised,
239 cartilage damage remains the cornerstone in the pathophysiology of OA ⁴¹, this was
240 reflected by its acceptance as an essential US feature. Unlike radiography, US can directly
241 visualise some parts of articular cartilage ⁴². Cartilage damage may not be uniform across
242 the entire joint ^{43, 44}. Therefore, the ability to consistently examine the exact same part of
243 cartilage, with US, will influence the reliability and validity of this measure. Given the general
244 opinion that US imaging is heavily operator dependent for image acquisition and
245 interpretation ^{45, 46}, investigating the reliability of grading cartilage damage would be critical
246 before inclusion into the US atlas. This reinforces the need for further refinement of
247 anatomical landmarks to guide probe positioning to ensure a standardised US imaging
248 acquisition procedure.

249

250 Current US grading systems applied to OA have been largely extrapolated from those
251 originally designed and validated to quantify inflammatory change in rheumatoid arthritis
252 (RA) ²⁵. Inflammation associated with OA is fundamentally different from that in RA, with OA
253 having lower levels of inflammatory proteins ⁴⁷, less pronounced synovitis ^{48, 49}, no response
254 to biologic drugs used in RA, and mediated primarily by the innate immune system ⁸. The
255 distinct difference of inflammation experienced in OA compared to RA^{11, 50}, reinforces the
256 need for OA-specific grading systems that truly depict the disease progression of first MTPJ
257 OA.

258

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

264 synovitis and joint space narrowing. A semiquantitative system enables quantification of
265 disease progression and provides insight into the degree of osteoarthritic change ²⁵. Issues
266 related to the subjectivity of semiquantitative systems have been highlighted, with challenges
267 in interpretation and differentiation between grading of disease severity ⁵⁰. This may be
268 reflective of the lack of consensus to guide grading and/or studies which have extrapolated
269 RA grading systems to OA. The acceptance of cartilage damage/thickness to be graded
270 using a continuous measure will mitigate issues with distinguishing between grades of
271 severity.

272

273 An US imaging acquisition procedure involves numerous variables that need to be
274 considered as part of examination, these include patient positioning, transducer orientation
275 and surfaces scanned. As it stands only two consensus-based guidelines exist to inform the
276 US imaging acquisition procedure to assess the first MTPJ ^{16, 51}. Despite this, there has been
277 marked inconsistency in the application of guidelines across studies ²⁶. The 2001 EULAR
278 guidelines included limited instructions on body position, transducer orientation and surfaces
279 of the first MTPJ to scan (supine position for the dorsal scans and prone position for the
280 plantar scans) ⁵¹. In 2017 a new EULAR-endorsed task force revised the standardised
281 procedures for US imaging in rheumatology ¹⁶. The updated EULAR guidelines for
282 performing US imaging of the first MTPJ addressed patient positioning, transducer
283 orientation, probe position (starting point) and, scanning technique ¹⁶. Despite this
284 enhancement, the revised guidelines still lack sufficient detail outlining specific anatomical
285 reference points to ensure a standardised US imaging acquisition procedure.

286

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

290 items were deemed essential when scanning both dorsal and plantar surfaces of the first
291 MTPJ. Unlike previous guidelines, the Delphi panel included first MTPJ positioning. Wherein
292 it was deemed essential that the first MTPJ should start in a neutral position (the position
293 where the foot is neither pronated nor supinated), then move through full range of motion
294 during the scanning procedure for both a dorsal and plantar scans. Consistent with both
295 2001⁵¹ and 2017 guidelines ¹⁶, a supine body position was deemed essential, however only
296 when performing a dorsal scan. Positioning the ankle/foot in neutral was deemed essential,
297 although only for a plantar scan. This is inconsistent with the 2017 guidelines which reported
298 a dorsiflexed foot position ¹⁶. The 2001 guideline ⁵¹ provided no further detail on how the
299 lower limb should be positioned. Regarding knee positioning, a flexed and extended knee
300 were accepted items for both dorsal and plantar scans respectively. Both knee positions are
301 consistent with the 2017 guidelines ¹⁶, however neither item were rated as essential.

302

303 The Delphi panel also deemed essential that the probe be orientated both longitudinally and
304 transverse when scanning the dorsal and plantar aspect of the first MTPJ. Specifically, for a
305 longitudinal scan the probe should be positioned on the plantar/dorsal aspect of the forefoot,
306 parallel to the first metatarsal head and proximal phalanx, joint line central to the image. In
307 conjunction with a transverse scan, where the probe should be positioned on the
308 plantar/dorsal aspect of the foot, perpendicular to the diaphysis of the first metatarsal then
309 move distally to the diaphysis of first proximal phalanx, joint line central to the image.

310 Previous guidelines provide limited descriptions of anatomical landmarks to guide probe
311 positioning. The revised 2017 guidelines only reported performing a transverse scan when
312 examining articular cartilage ¹⁶. The findings of the Delphi support the application of a
313 multiplanar technique when examining the first MTPJ. A multiplanar technique is crucial in
314 cases where one feature (e.g. joint effusion or osteophyte) is obstructing the view of another
315 feature under examination, or when there is severe structural changes, often associated with
316 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**

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

347

348 **Conclusion**

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

355

356 **List of Abbreviations**

357 Osteoarthritis: OA

358 Metatarsophalangeal Joint: MTPJ

359 Ultrasound: US

360 Osteoarthritis Research Society International: OARSI

361 United Kingdom: UK

362 European League Against Rheumatism: EULAR

363 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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381 Council of New Zealand. This organisation had no role in the study design, collection,
382 analysis, or interpretation of the data, or in the decision to submit the article for publication.

383

384 **Authors' contributions**

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

391

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395 research.

396

397 **Availability of data and materials**

398 All available data is provided within the manuscript

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558

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

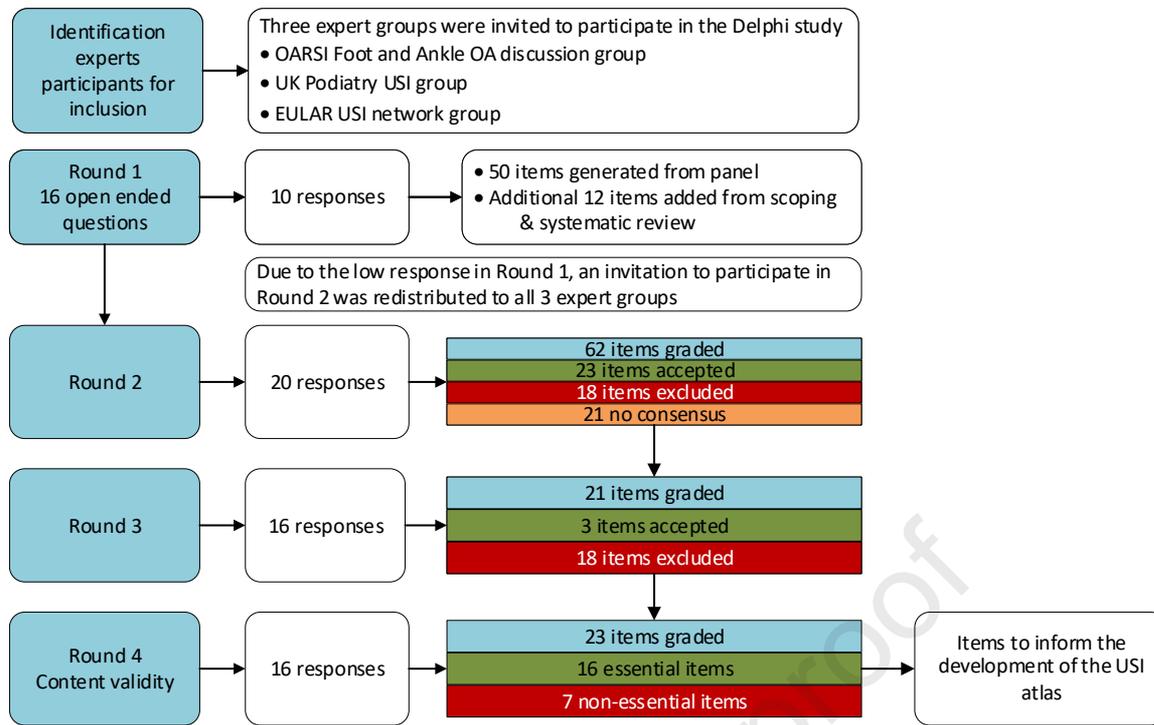
Table 3 All accepted items from the Delphi survey used to inform the methodological development of an US atlas to grade the degree of osteoarthritic change in the first MTPJ.

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.

Conflict of interest

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.

Declaration of Funding

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

Role of the funding source

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.

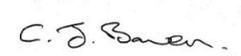
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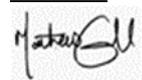
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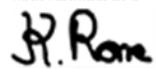
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