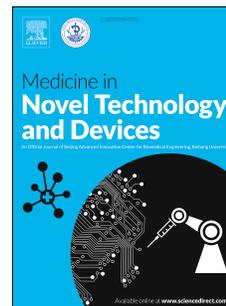


# Journal Pre-proof

An Instrument for Methodological Quality Assessment of Single-Subject Finite Element Analysis Used in Computational Orthopaedics

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1 **An Instrument for Methodological Quality Assessment of Single-Subject Finite Element**  
2 **Analysis Used in Computational Orthopaedics**

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Journal Pre-proof

32 **An Instrument for Methodological Quality Assessment of Subject-Specific Finite**  
33 **Element Analysis Used in Computational Orthopaedics**

34

35 **Abstract**

36 The methodological quality of subject-specific finite element analysis papers depends on the  
37 rigor of the study design and detailed description of key elements, while assessment  
38 instruments are often confined to clinical trials or quasi-experiments. This study aims to  
39 present an instrument for methodological quality assessment of single-subject finite element  
40 analysis used in computational orthopaedics (MQSSFE). Based upon existing instruments  
41 and relevant review papers, a pilot version was developed consisting of 37 items with 6  
42 domains, including study design and presentation of findings, subject recruitment, model  
43 reconstruction and configuration, boundary and loading conditions (simulation), model  
44 verification and validation, and model assumption and validity. We interviewed four experts  
45 in the field to assess the face validity and refined the instrument. The instrument was tested  
46 for interrater reliability among two assessors on nine finite element study papers. Also, the  
47 criterion validity was evaluated by comparing the similarity of the MQSSFE and the  
48 modified Down and Black instrument. The intraclass correlation coefficient was 0.965, while  
49 the MQSSFE was significantly moderately correlated with the modified Down and Black  
50 instruments ( $r = 0.61$ ). We believed that MQSSFE was adequately appropriate, reliable, and  
51 valid for assessing the methodological quality for finite element studies used in  
52 computational orthopaedics. The instrument could facilitate quality assessment in the  
53 systematic reviews of finite element models and checklists for fidelity.

54

55 **Keywords: finite element model; simulation; validation and verification; mesh**  
56 **convergence; uncertainty analysis**

57

**58 1. Introduction**

59           The finite element method or analysis is a computational tool or numerical simulation  
60 to solve complex engineering and mathematical problems. The basic concept of the finite  
61 element method is to subdivide or discretize large and complex systems into smaller and  
62 simpler parts, named finite elements that locally approximate the original complex equations.  
63 This approach is advantageous in presenting complex geometry, including dissimilar  
64 materials, ease for computation, and analysis of local effects [1]. The finite element method  
65 was believed to be originated in the early 1940s for structural analysis problems in civil and  
66 aeronautical engineering, which was subsequently coined by Argyris and Clough in 1960 [2].  
67 It was later widely used to design and develop engineering products to minimize the weight,  
68 materials, and costs that improved the design process and cycle [3].

69           Eventually, engineering has submerged in medicine with the finite element as one of  
70 the instigators. Dentistry or Orthodontics is one of the pioneers of biomechanics and  
71 biomaterial investigations using finite element methods that could hardly be achieved *in vivo*  
72 [4]. In the 1990s, there were more than 700 publications relating to finite element simulation  
73 on orthodontics, despite the scarcity in computer facilities by that time [5]. On the other hand,  
74 computational orthopaedics represented another major branch and has been applied for more  
75 than 40 years [6], particularly in the evaluations of knee and hip replacement designs [6-8].  
76 With the advancement of computing power and software, the scope of computational  
77 orthopaedics has extended to the region composed of numerous sophisticated parts and  
78 complex loading conditions, including the spine [9] and the foot-and-ankle complex [8,10].  
79 The versatile platform not only uncovered the mechanism of pathologies or injuries [9,11,12]  
80 but also dedicated to other applications, such as footwear design [13], surgical planning  
81 [14,15], implant customization [16,17], physiotherapeutic intervention [18], prosthetics, and

82 orthotics [19,20], and sports science and medicine [21].

83 While the impact of the finite element method in translational and pre-clinical  
84 research has been affirmed, there have been concerns about the quality of simulation papers.  
85 Some reviews on finite element methods pointed out that many simulation papers lacked  
86 adequate model verification and validation [22], while some studies were not actually  
87 modeling the pathological condition of interest and overclaimed the implications [11]. It is  
88 calling for some quality controls on the research using finite element analysis. For example,  
89 the journal, *Clinical Biomechanics*, imposed strict requirements on the inclusion of necessary  
90 components. Reports shall also be based on the specific question of clinical interest [23].  
91 Similarly, the *Journal of Orthopaedic Translation* requires explicit statements to highlight the  
92 translational potential of the study. Some other clinical journals may regard subject-specific  
93 finite element models as a nonclinical study or a case study that are not welcome; otherwise,  
94 adequate sample size is required to attain a case series with a relative low level of evidence  
95 [24]. Furthermore, there has been lacking guidelines or quality assessment instruments for  
96 finite element models, whereas methodological quality assessment has been imperative and  
97 undeniable in systematic reviews, such as that on randomized controlled trials [25].

98 To this end, we propose an instrument, Methodological Quality Assessment of  
99 Subject-Specific Finite Element Analysis Used in Computational Orthopaedics (MQSSFE),  
100 which aimed to evaluate methodological quality on finite element studies, particularly on the  
101 inclusion of critical elements. This paper would outline the development domains of the  
102 instrument and the evaluation of validity and reliability.

103

## 104 **2. Materials and methods**

### 105 *2.1 Development of Instrument and Face Validity*

106           The first author developed the instrument based on an integration of other  
107 methodological quality assessment instruments [26,27], and the incorporation of relevant  
108 review paper discussion [10,11,22]. The face validity of the instrument was facilitated by  
109 interviews with experts (the 5<sup>th</sup>, 6<sup>th</sup>, and 7<sup>th</sup> author) on finite element analysis. One  
110 biomechanical expert (the 4<sup>th</sup> author) that was not dedicated to finite element analysis was  
111 also interviewed to account for potential prejudice. The instrument was revised to make sure  
112 that it is understandable and trivial. Necessary remarks were added to help readers better  
113 answer the instrument items. The details of the MQSSFE is shown in Table 1 and attached in  
114 the Appendix.

## 115 *2.2 Inter-rater Reliability*

116           We planned to evaluate the inter-rater reliability of MQSSFE between two assessors  
117 (2<sup>nd</sup> and 3<sup>rd</sup> author) using a brief review of recent finite element study articles. The assessors  
118 were, respectively, postdoctoral fellow and Ph.D. candidate working on finite element  
119 analysis of the foot and ankle.

120           Literature search was conducted by the first author on the electronic database, ISI  
121 Web of sciences to retrieve finite element studies related to the foot and ankle in order to  
122 match the expertise of the assessors. The searches were conducted on 15 Dec 2020 using the  
123 keywords “finite element” AND (“foot” OR ankle”) in the topic field. The articles shall be  
124 original research in English, published in 2020, under the SCI category and orthopaedics  
125 research area. Articles that were not dedicated to a clinical condition or intervention were  
126 excluded. There were nine articles eligible for the review. Three out of twelve articles from  
127 the initial search were excluded because they were either not describing a clinical condition  
128 or did not consider any human body parts in the model.

129 Reliability was determined by the correlation coefficient, ICC (2,1), absolute  
130 agreement for the total score of MQSSFE. An ICC of above 0.75 was considered as good and  
131 acceptable reliability [28].

### 132 *2.3 Criterion Validity*

133 Besides, the two assessors also completed a modified version of the Down and Black  
134 instrument [26] and compared to that of the MQSSFE to facilitate the evaluation of criterion  
135 validity. The Down and Black instrument was a checklist to evaluate the quality of reporting,  
136 power, internal and external validity for randomized and non-randomized studies in  
137 healthcare interventions [26]. The original instrument consisted of 27 questions. However, it  
138 was commonly modified to accommodate different scope of studies, such as sports [29] and  
139 psychiatry [30]. For the modified Down and Black instrument, the original 27 Items were  
140 crunched down to 12 items. Item 8, 9, 14, 15, 17, 19, 21, 22, 23, 24, and 26 were excluded  
141 because they were not applicable to the study design of the finite element model. Item 7, 11,  
142 18, 25, and 27 were excluded because these items were related to statistics that did not apply  
143 to single-subject design. The Spearman rank correlation test was run to determine the  
144 correlation between the total scores of MQSSFE and the modified Down and Black  
145 instrument.

146

## 147 **3. Results**

### 148 *3.1 Outline of the instrument*

149 There were a total of 37 items in the instrument that are categorized into six domains.  
150 They include study design and presentation of findings (item 1 to item 8), subject recruitment  
151 (item 9 to 12), model reconstruction and configuration (item 13 to 20), boundary and loading

152 conditions, simulation (item 21 to 26), model verification and validation (item 27 to 31), and  
153 model assumption and validity (item 32 to 37).

154 For the study design and presentation of findings, a clear and well-defined research  
155 hypothesis, aim, or objective is crucial in the introduction (item 1). Next, item 2 and item 3  
156 accounted for the data dredging issues. If the study is exploratory without a well-defined and  
157 justified set of outcome parameters (data dredging), the spectrum of the endpoints shall be  
158 justified (item 3). Also, the critical information, including outcome measures (item 4 and item  
159 6), time-points (item 5), and key findings (item 7 and item 8), shall be described clearly and  
160 correctly.

161 For the domain of subject recruitment, Item 9 and item 10 describe the model  
162 subject's characteristics. Item 11 determined whether the subject recruitment is appropriate,  
163 while item 12 noted whether the studies have described the relevant clinical conditions  
164 clearly.

165 Item 13 to item 20 examine the description of the model reconstruction and  
166 configuration process, including model reconstruction modality (item 13) and specifications  
167 (item 14), the control of model reconstruction, alignment, and assembly process (item 15 to  
168 item 17). The mesh creation, material property, and interaction property shall also be clearly  
169 stated (item 18 to item 20). On the other hand, the boundary and loading conditions shall be  
170 clearly described (item 21). The simulation scenario shall reflect the common activity or load  
171 case of the targeted clinical conditions (item 22) with appropriate and sufficient assignment  
172 of loading conditions, such as muscle force and ground reaction force, ideally acquired from  
173 the model subject (item 23 to item 25). Eventually, the type of analysis (static or dynamic)  
174 and the software used for the analysis shall be explicitly declared.

175 Model verification and validation play an essential role in finite element analysis. The  
176 processes and the results for model verification and validation shall be described clearly (item  
177 27 to item 30). Some studies may also compare the findings with existing relevant studies  
178 (item 31). Besides, model assumption and simplification shall be discussed in the limitations,  
179 including those on model reconstruction/configuration and material properties (item 32),  
180 boundary and loading conditions (item 33), and model validation and verification (item 34).  
181 Furthermore, how the findings of the finite element model could be translated into  
182 applications shall be mentioned with the internal and external validity of the findings  
183 addressed (item 35 and item 36).

### 184 *3.2 Demonstration of MQSSF*

185 As shown in Table 2, a literature review on the finite element studies of the foot and  
186 ankle. Nine eligible articles were retrieved for analysis [18,31-38]. One study investigated  
187 foot pathology [30] while another study targeted on a physiotherapeutic intervention [18].  
188 The other studies were related to surgical interventions [31-35,37,38]. A simple loading case,  
189 standing, was adopted in most of the literature, while Chen et al. [18] simulated a relatively  
190 complicated running scenario. Some other studies explored the biomechanics in the different  
191 foot-ankle positions [37,38].

192 In terms of the outcome of the MQSSF (Table 3), the average total score was 21.3  
193 (range 17 to 34.5). The papers generally performed well in the description of technical  
194 context, including key findings (item 7), technical specification and the process of model  
195 reconstruction (item 14 and item 16), material properties (item 19), boundary and loading  
196 conditions (item 20), and interactions (item 21). They also addressed the model assumption in  
197 reconstruction and material properties (item 32) and avoided unplanned analysis (item 2).  
198 However, the papers generally lost points in justifying or supporting the internal and external

199 validity of the study (item 11 and item 36). They seemed to avoid discussing the limitations  
200 regarding model validation (item 34). Some studies did not describe the relative position or  
201 assembly of the implant clearly (item 17). Most of the studies simulated standing only, which  
202 may not adequately represent the common loading conditions (such as walking) in daily  
203 activities (item 22). Also, muscle forces were often neglected or overly simplified (item 24  
204 and item 25).

### 205 *3.3 Inter-rater reliability*

206 There was no statistically significant difference in the total MQSSFEE scores between  
207 the two assessors ( $p = 0.842$ ). The intraclass correlation coefficient, ICC (2,1), was 0.965,  
208 95%CI 0.855 to 0.992, which indicated good and acceptable reliability.

### 209 *3.4 Criterion validity*

210 There was a positive, large, and significant association level ( $r = 0.61$ ,  $p = 0.007$ )  
211 between the MQSSFEE scores and the modified Down and Black score [26]. However, it shall  
212 be noted that MQSSFEE assessed more constructs than the modified Down and Black  
213 instruments.

## 214 **4. Discussion**

215 Physicians are increasingly counting on computational methods, such as the finite  
216 element model, to provide insights on orthopaedic sciences and the design of implants or  
217 other devices. Computational methods put less physical, financial, and technical constraints  
218 that can complement traditional *in vivo* or *in vitro* experiments [39]. However, compared to  
219 clinical trials, simulation studies imposed less cost and loosely regulated, could be easily  
220 abused, and were criticized for the lack of quality control. Some researchers could take  
221 advantage of the convenient tool for tweaking output by tuning different materials or loading  
222 conditions using overly simplified and inaccurate models without adequate verification and

223 validation. It was believed that the complex finite element models are highly susceptible to  
224 the “garbage-in, garbage-out” phenomenon since the outputs are highly dependent on the  
225 quality of the input and model [39]. In fact, computational methods play an important role in  
226 translational medicine to inform design and practice. The consequence of poor-quality studies  
227 or malpractice could be disastrous. It is imperative and calling for an instrument or checklist  
228 to substantiate the fidelity and the clinical utility of the simulation.

229 Our 37-item MQSSFE has demonstrated adequate reliability and validity. However,  
230 the evaluation process had focused on the finite element models of the foot and ankle;  
231 nevertheless, we envisioned that the instrument could be applied to other areas in  
232 computational orthopaedics. It shall be noted that different areas in computational  
233 orthopaedics may have different interests and thus endpoints. For example, investigations on  
234 implants may focus on the tribology and wear of the implant [40]. Simulations of some body  
235 parts were compelled to indirect validation due to experimental constraints [41]. On the other  
236 hand, we did not evaluate construct validity and internal consistency because we believed that  
237 the scale did not manifest any abstract construct. The items within each domain could also be  
238 independent.

239 Model credibility is of utmost importance for clinicians or scientists to extrapolate  
240 implications and decisions based on the model predictions [42]. In order words, they shall  
241 warrant sufficient accuracy or reliability for the intended use [42] and closely resemble the  
242 concepts of internal and external validity in clinical studies. There are three concerns  
243 regarding model credibility. The first concern is the correctness of the model or the  
244 calculation. Secondly, the accuracy of the model prediction shall be adequately accurate to  
245 answer the scientific question. Thirdly, potential errors and uncertainties inherited in the  
246 model prediction shall be addressed since the reality of interest is always stochastic while the  
247 model prediction is naturally deterministic. Model verification and validation represent ways

248 to identify and account for errors or uncertainties due to model implementation and  
249 formulation [41].

250 Model verification justifies the accuracy of the mathematical model and its solutions  
251 [43]. While we always assumed that the finite element code has been verified by the software  
252 developing companies, errors are sourced from the discretization of geometry or analysis  
253 time [41]. Model verification is contemplated by the mesh convergence test, which is often  
254 concluded by the size and the number of elements or nodes after an iterative refinement of  
255 mesh quality on the percentage change of a solution parameter [41]. Model verification using  
256 mesh convergence test is highly recommended since it provides information on the baseline  
257 discretization error for the readers [41]. Research on some complicated models, such as the  
258 spine and the foot-and-ankle complex, suggested that the mesh refinement could be regarded  
259 as sufficient when the change of the output solution was less than 5% [44,45].

260 Model validation is the process of determining the degree of the model that can  
261 accurately represent the reality of interest for the intended use [41]. Since the origin of the  
262 computational model is to simulate phenomena that cannot be easily measured  
263 experimentally or with unknown model inputs [22], some researchers compromised the  
264 definition and approach of model validation. It shall compare the model prediction to the  
265 golden standard (i.e., physical experiment data) for the evaluation of modeling error [42].  
266 Validation experiments or direct validation are specifically designed for comparison rather  
267 than to address the scientific hypothesis [42]. Therefore, the validation process does not  
268 assume that physical experiments are more accurate and reliable to manifest the reality of  
269 interest [42,46]. Ideally, the validation experiment or metric shall be directly related to the  
270 research problem or primary outcome [42,46]. Given the paradox of the necessity of  
271 simulation if physical experiment could be arranged, the central problem of validation  
272 experiment is always on time, cost, feasibility, and complexity. Often, lower-order data

273 (instead of the primary outcome) are treated as the validation metric to provide fundamental  
274 confidence. In this case, additional evidence or other measurement data shall be supplied to  
275 improve model credibility [42,44]. Besides, indirect validation is another alternative that  
276 compares the prediction outcomes to existing literature, which are less favorable since the  
277 quality control, errors, and variability are unknown [42,44].

278 Qualitative observation on the fringe plots was used to relate the model to the  
279 experimental findings and thus facilitate validation. Therefore, a consistent color or fringe  
280 scale is essential. A typical example is the plantar pressure distribution at different walking  
281 phases [47]. Statistical analysis on validation could be conducted by the measure of  
282 correlation, ideally enforcing the slope of the regression line as one [41]. Nevertheless, Bland  
283 and Altman [48] opposed the approach because the measure of agreement shall be adopted.  
284 They proposed a form of analysis (Bland-Altman plot) to account for repeatability and  
285 reproducibility.

286 Study designs are critical elements in clinical research. Researchers may plan to  
287 conduct a case-control or cohort trial; recruit subjects, and assign them into targeted or  
288 control groups in clinical studies. Some demanding study designs, such as the randomized  
289 controlled trial, are designed to address the internal and external validity issues. In the  
290 computational study, particularly for single-subject design, the same method may not be  
291 applicable. Instead, researchers manipulate the input variables of the single-subject model in  
292 simulation and postulate the responses using the design of computer-based experiment  
293 approach [6]. While a simple comparative analysis compares the performance of two or more  
294 conditions, parametric analyses are often implemented to understand the severity of the  
295 pathology or impact of design parameters [47,49,50] using a full or fractional factorial  
296 approach [50,51]. The approach sweeps the effect of the clinical or design features and  
297 understand its contribution, whilst keeping the other parameters constant [6]. In lieu, some

298 studies adopted a similar approach but prefer the probabilistic technique (Monte Carlo  
299 Approach) to generate input by a defined distribution [52]. Besides targeting the primary  
300 research interest, parametric analysis could also be used to explore the sensitivity of  
301 modelling assumptions, such as modelling, surgical, and patient variability, that correspond to  
302 internal and external validity considerations (item 35 and 36). The significance of sensitivity  
303 analysis lies in its potential to quantify the uncertainty or validity of the input to better  
304 understand their influence on model prediction [42].

305         The single-subject and subject-specific approach is a typical study design in the finite  
306 element analysis that hindered the external validity or the generalizability of the findings.  
307 Some research adopted population-based subject-specific models [53,54]. However, this  
308 method may not be feasible to apply in some sophisticated models or models with complex  
309 boundary and loading conditions. While some research dedicated to the development of  
310 statistical models [55], most of the studies claimed that the model subject was representative  
311 of the population to account for the generalizability and endeavoured to improve internal  
312 validity by mesh convergence test, uncertainty or variability analysis [49,56]. However, the  
313 single-subject subject-specific nature of the study is often confined to the geometry and  
314 model reconstruction. Some studies overlooked or adopted loading conditions or muscle  
315 forces from other sources instead of the model subject. Besides, some clinical conditions  
316 often use a modified version of the normal model as a surrogate, which may not adequately  
317 represent the clinical features and shall be interpreted carefully.

## 318 5. Conclusions

319 Model fidelity is imperative to the credibility and translation potential of the model  
320 prediction. In this study, we developed an instrument to evaluate the methodological quality  
321 for single-subject finite element studies dedicated to the area of orthopaedics. The instrument

322 was optimized in face validity section and demonstrated good reliability and validity in the  
323 intraclass correlation and criterion validity tests. The instrument highlights the necessity in  
324 the clear description of critical elements in finite element analysis. Moreover, it also stressed  
325 the importance of the study design, validation, verification, and uncertainty analysis to  
326 determine the limits of model application and to prevent over-extrapolation of findings. The  
327 instrument can facilitate quality assessment in the systematic reviews of finite element  
328 models and checklists for fidelity.

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### 336 **Conflict of Interest Statement**

337 W-K.L. is an employee of Li Ning Sports Goods Company Limited. The company  
338 had no role in the design of this study, execution, analyses, interpretation of the data or  
339 decision to submit results. There is no direct connection and conflict of interest to this article.  
340 The other authors declare that there are no conflicts of interest.

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484

485

486 **Tables**487 Table 1 Methodological Quality Assessment of Single-Subject Finite Element Analysis Used  
488 in Computational Orthopaedics (MQSSFE)

	Question	Yes	No	Score
<b>Study Design and Presentation of Findings</b>				
1	Was the hypothesis/aim/objective of the study clearly described?			
2	Were all analyses planned at the outset of study? <i>Answer NO for unplanned analysis/sub-analysis, unable to determine.</i>			
3	If data dredging (establish objectives, hypothesis and endpoint parameters without scientific reason) was used, was the spectrum of the data justified by any concepts? <i>Answer YES if no data dredging, NO if unable to determine</i>			
4	Were <u>ALL</u> the outcome measures and parameters (including all data reduction methods or derived parameters) clearly described and defined in the Objectives or Methods section? <i>Answer NO if they are only defined in results or discussion</i>			
5	Were the time points or period for <u>ALL</u> the outcome measures clearly described? <i>Answer YES if not applicable</i>			
6	Were the main outcome measures appropriate to describe the targeted conditions ? <i>Answer NO if unable to determine</i>			
7	Were the key findings described clearly?			
8	Were <u>ALL</u> the contour plots that were used for comparison presented with the same colour scale?			
<b>Subject Recruitment</b>				
9	Were the characteristics of the model subject clearly described?			
10	Were the principal confounders of the model subject clearly described ? (Age, sex, or body weight, and height)			
11	Was the model subject participated in the study representative of the population with the targeted clinical conditions or demographic features ? (e.g. answer NO if simulating a pathology by modifying a normal subject model; or scaling an adult model to a child model)			
12	Were the targeted intervention or clinical condition clearly described ? (with details in the severity, class, design/dimensions of implants, or details in surgical surgery)			
<b>Model Reconstruction and Configuration</b>				
13	Was the model reconstruction modality for the body parts and <u>ALL</u> other items, such as implants, clearly described (e.g. MRI, 3D-scanning, CAD) ?			
14	Were <u>ALL</u> important technical specifications (e.g. resolution) for the reconstruction modality clearly described ?			
15	Was the posture or position of the body parts controlled during the acquisition process (e.g. MRI, CT) of the model reconstruction ?			

16	Were the model reconstruction methods for <u>ALL</u> components clearly described including those requiring additional procedures (e.g. connecting points for drawing ligaments from MRI)?			
17	Were the orientation or relative position among the components of the model assembly (where appropriate) clearly described? <i>Answer YES if not applicable</i>			
18	Was the type of mesh for <u>ALL</u> components, including the order of magnitude of the elements, clearly described ?			
19	Were the material properties for <u>ALL</u> components clearly described and justified ? (e.g. with reference)			
20	Were <u>ALL</u> the contact or interaction behaviours in the model clearly described and justified?			
Boundary and Loading Condition (Simulation)				
21	Were the boundary and loading conditions clearly described ?			
22	Was the boundary and loading condition sufficiently simulating the common activity/scenario of the conditions ? (e.g. if the research or inference is targeted to ambulation or daily activities, simulations of balanced standing or pre-set compressive load are not sufficient)			
23	Was the model driven by the boundary and loading conditions acquired from the same model subject?			
24	Was loading condition on the scenario sufficiently and appropriately considered in the simulation? (e.g. muscle force, boundary force, inertia force)			
25	Was the loading condition acquired from the same model subject?			
26	Were the software (e.g. Abaqus, Ansys), type of analysis (e.g. quasi-static, dynamic), <u>AND</u> solver (e.g. standard, explicit) clearly described ? (solver can be regarded as clearly described if it is obvious to the type of analysis)			
Model Verification and Validation				
27	Were the methods of mesh convergence or other verification tests conducted and clearly described?			
28	Were the model verification conducted and results presented clearly; and that the model was justified acceptable ?			
29	Were direct model validation (with experiment) conducted and described clearly? <i>Answer YES if the authors had direct model validation previously with reference.</i>			
30	Were the model validation conducted and results presented clearly; and that the model was justified acceptable ?			
31	Were the model prediction or validation findings compared to relevant studies ?			
Model Assumption and Validity				
32	Were the model assumptions or simplifications on model reconstruction/configuration <u>AND</u> material properties discussed?			
33	Were the model assumptions or simplifications on the boundary and loading conditions discussed?			

34	Were the limitations of model validation discussed? (e.g. differences in case scenario; differences between validation metric and primary outcome)			
35	Was the limitation on external validity, single-subject, and subject-specific design discussed?			
36	Were there any attempts to improve or discuss internal validity (such as mesh convergence test), uncertainty and variability in the study?			
37	Was there any discussion, highlights or content on the implications or translation potential of the research findings? <i>Answer NO if there are only bold claims without making use of the result findings or key concepts</i>			
				Sum:

489 Yes scores one point; No scores zero point.

490

491 Table 2. Literature review of recent finite element studies of the foot and ankle.

Author	Clinical problem	Simulation Scenario	Outcome measures
Can et al [38]	Tenodesis reconstruction, including Pisani interosseous talocalcaneal ligament, Schon cervical ligament, Choise calcaneofibular ligament, Schon triligamentous, and Mann triligamentous reconstruction	Different ankle positions	Kinematics of subtalar joint, contact pressure of subtalar joint, stress in reconstructed grafts
Cifuentes-De La Portilla et al [31]	Midfoot fusion for adult acquired flatfoot, including talonavicular joint, naviculocuneiform, and cuneometatarsal joint	Standing	Spring ligament stress, arch height, arch length
Cifuentes-De La Portilla et al [32]	Hindfoot joint arthrodesis for adult acquired flatfoot, including talonavicular arthrodesis, calcaneocuboid arthrodesis, triple arthrodesis	Standing	Maximum principal stress of spring ligament, forefoot bones, and hindfoot bones
Chen et al [18]	Fascia taping, low-dye taping	Running	Maximal strains of the proximal, middle and distal plantar fascia, maximal subtalar eversion, minimal navicular height
Fan et al [33]	Four screw fixations for talus neck fracture, including dual screws and cross screws in anteroposterior and posteroanterior directions	Single-leg standing	Maximum stress and maximum displacement of talus and fixation.
Qiang et al [34]	Different placement of sustentaculum screw for calcaneal fractures	Standing	Von Mises stress, contact area and maximal displacement of the subtalar joint
Ramlee et al [35]	External fixator for pilon fracture under normal, osteoarthritis, and osteoporosis conditions	Stance and swing	Von Mises stress and displacement for bones and fixator
Van Zwan et al [36]	Heel ulcers for bedridden patients	Different foot postures on	Contact pressure and maximum shear strain of the heel and calf

		bed	
Wang et al [37]	Five kinds of three-screw configuration used for ankle arthrodesis in traumatic ankle arthritis, including	Midstance, standing, dorsiflexion, internal and external rotation of ankle	Von Mises stress of tibia and talus, maximum and average micromotion and pressure of the tibiotalar surface

492

493

Journal Pre-proof

494 Table 3 Demonstration of MQSSF E for nine reviewed articles

	Can et al [38]	Cifuentes-De La Portilla et al [31]	Cifuentes-De La Portilla et al [32]	Chen et al [18]	Fan et al [33]	Qiang et al [34]	Ramlee et al [35]	Van Zwan et al [36]	Wang et al [37]	Sum
1	?	?	?	+	-	+	?	?	?	5
2	+	+	?	+	+	+	+	+	+	8.5
3	+	?	?	+	-	+	+	+	+	7
4	-	-	-	+	-	+	-	+	+	4
5	+	?	?	+	+	+	-	+	+	7
6	+	?	-	+	+	+	+	+	+	7.5
7	?	+	+	+	+	+	?	+	+	8
8	+	-	?	+	-	+	+	-	-	4.5
9	+	?	+	+	+	+	-	+	+	7.5
10	+	?	+	+	+	+	-	?	+	7
11	-	-	-	+	-	-	-	-	-	1
12	+	?	?	+	+	-	+	+	+	7
13	+	?	?	+	+	-	+	+	+	7
14	+	+	+	+	+	+	+	+	+	9
15	-	-	-	+	+	-	-	-	+	3
16	+	+	+	+	+	+	+	+	+	9
17	?	-	-	?	?	-	-	?	?	2.5
18	-	-	-	+	-	-	+	+	+	4
19	+	?	?	+	+	+	+	+	+	8
20	+	?	?	+	+	+	+	+	+	8
21	+	+	+	+	+	+	+	+	+	9
22	-	-	-	+	-	-	?	?	-	2
23	-	-	-	+	-	-	-	?	-	1.5
24	-	?	?	+	-	-	-	-	-	2
25	-	-	-	+	-	-	-	-	-	1
26	?	?	?	+	-	-	?	?	+	4.5
27	+	+	+	+	-	-	-	+	?	5.5
28	+	?	?	+	-	-	-	-	-	3
29	?	+	+	+	-	-	-	?	-	4
30	+	?	?	+	-	-	-	-	-	3
31	+	?	?	+	-	+	+	+	-	6
32	+	+	?	+	+	+	+	+	+	8.5
33	-	+	?	+	+	-	+	-	-	4.5
34	-	-	-	-	-	-	-	-	?	0.5
35	+	-	?	+	+	-	-	+	+	5.5
36	-	-	-	-	-	-	-	-	?	0.5
37	?	?	?	+	+	-	?	+	+	6
<b>Sum:</b>	23	17	17	34.5	18.5	17	17.5	23.5	23.5	

495 +: Both assessors scored the item; -: Both assessors did not score the item; ?: The assessors  
496 gave inconsistent results