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¹ Clinically useful finite element models of

² the natural ankle – a review

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- 13
- 14 Abstract
- 15 Background

16 Biomechanical simulation of the foot and ankle complex is a growing research area but compared to

17 simulation of joints such as hip and knee, it has been under investigated and lacks consistency in

18 research methodology. The methodology is variable, data is heterogenous and there are no clear

19 output criteria. Therefore, it is very difficult to correlate clinically and draw meaningful inferences.

20 Methods

21 The focus of this review is finite element simulation of the native ankle joint and we will explore: the

22 different research questions asked, the model designs used, ways the model rigour has been ensured,

23 the different output parameters of interest and the clinical impact and relevance of these studies.

24 Findings

The 72 published studies explored in this review demonstrate wide variability in approach. Many studies demonstrated a preference for simplicity when representing different tissues, with the majority using linear isotropic material properties to represent the bone, cartilage and ligaments; this
allows the models to be complex in another way such as to include more bones or complex loading.
Most studies were validated against experimental or in vivo data, but a large proportion (40%) of
studies were not validated at all, which is an area of concern.

31 Interpretation

- 32 Finite element simulation of the ankle shows promise as a clinical tool for improving outcomes.
- 33 Standardisation of model creation and standardisation of reporting would increase trust, and enable
- 34 independent validation, through which successful clinical application of the research could be realised.
- 35 Keywords: Ankle; Finite Element; Clinical relevance; Modelling; Orthopaedics
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38 1 Introduction

Finite Element (FE) Analysis of the foot and ankle has been a rapidly growing field in the past two decades, and it shows great promise as a tool to inform clinical planning and treatment. As simulation studies do not put the patient at any risk, it is possible to assess the potential of more risky and radical treatments, and to predict patient-specific outcomes of surgical treatment enabling optimisation prior to intervention. The purpose of this literature review was to capture the current trends in simulation studies of the natural ankle, and explore ways in which their clinical translation can be facilitated.

45 1.1 Review methodology

The literature was identified from the Scopus database using the search words 'ankle' AND 'finite element', OR 'in silico', OR 'computational' OR 'tibiotalar'. No limit was set on the publication date and the search was performed in December 2022; this resulted in 144 documents. These were then reviewed and papers excluded if:

- The primary focus of the paper was on a prosthesis rather than the natural ankle
- The study did not include the natural ankle or whole foot
- Finite element methods were not used as a primary part of the study

This resulted in 72 studies which were investigated; themes within these were identified and used to
structure this article.

55 1.2 Clinical Need

FE models have been utilised extensively in the knee to evaluate the biomechanics of the cruciate ligaments [3] and there is certainly a role for models in the ankle to similarly research the pathomechanics of ankle instability and ligament injury. The effect of each sequential ligament injury (lateral, syndesmotic and medial) in multi-ligament patterns, as well as repair of each in turn, could be examined to determine the effect on joint displacement and contact stresses, providing information on optimal repair strategy, prognosis, and how aggressively such injuries should be 62 treated. The timing of surgery after ligament injury of the ankle has been identified as a priority for 63 UK Foot & Ankle research [4]. Furthermore, FE models could be utilised to optimise techniques (e.g. number of bone anchors and bone anchor positions in lateral ligament reconstruction, effect of 64 65 fibretape or hamstring augmentation of lateral ligament reconstruction, screws versus dynamic 66 stabilisation of the syndesmosis) as well as quantify the effect of bony alignment (e.g. heel varus) and 67 the impact of correction. FE could also be a useful tool in examining fixation at the enthesis – with 68 previous groups using this method to evaluate and compare rotator cuff repair methods [5]. In this 69 way FE could also examine treatment of insertional Achilles tendinopathy and re-attachment 70 strategies.

71 Osteoporotic ankle fractures are the third most common fragility fracture [6] with an anticipated 72 increase in incidence with an aging population. FE models have been used to evaluate fixation 73 methods in osteoporotic bone in the proximal humerus and proximal femur [7]. An in silico ankle 74 model based on osteoporotic bone could provide useful insights in optimising fixation and minimising 75 risks of fatigue failure of implants. Locking technology, fibula-pro-tibia screws, number of screws and 76 alternative fixation strategies such as tibio-talo-calcaneal nailing and fibular nailing could be examined 77 to assess strain across the fracture site as well as loading of the implant expanding our understanding 78 of these difficult injuries and the most biomechanically sound strategies for fixing them.

In the longer term, patient-specific FE models derived from the individual's CT may have a role both in augmenting the design of customised instrumentation in arthroplasty, as well as pre-operative planning in re-alignment surgery to enhance biomechanical outcome for example in supramalleolar osteotomy for treatment of eccentric ankle arthritis.

One of the critical barriers to the translation of FE models into clinical practice is trust; clinicians need to be sure that the data from a simulation can be relied upon to be correct before any treatment decisions are made. A first step towards this is to improve clinical understanding of how such models

work, what they can (and cannot) represent, and what questions to ask in order to ascertain how
trustworthy a model and its results are.

88 1.3 Biomechanics Simulation Overview

89 Finite element (FE) research of the ankle has focussed on a range of applications such as impact [8, 9], injury [10-14], surgery [15-20], shoe [21, 22] or orthotic [23] design, and arthroplasty [24-31]. 90 91 Depending on their application, these models have been formulated of several structures (Figure 1); 92 some models consider only one bone [25, 29, 32], while others model just the bones of the ankle [1, 93 15, 16, 18, 28, 30, 31, 33-45], and some have generated whole foot models which often include the 94 soft tissues encapsulating the bones [2, 8, 9, 11-14, 21-23, 46-66]. The level of complexity required 95 from any model is dependent on the research question being asked and it is the role of the research 96 team to ensure the model captures all the key factors which may affect the result. This has led to large 97 variability in research methods limiting the opportunities for independent validation.

98 Reproducibility and standardisation are contentious issues within orthopaedic modelling [67]; 99 reporting methods to ensure they are reproducible and robust is key to increasing confidence in model 100 outputs. However, this does not come without its challenges and there is currently a lack of 101 standardisation of methods in FE of the foot and ankle. Differences between methods start from 102 model generation and can be seen through to results analysis.

103 The initial step in creating a FE model is replication of the patient tissue geometry within the computer 104 from medical scans. Digitisation of the patient geometry can be achieved through segmentation of 105 both Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) images using a range of 106 software; this provides accurate patient specific tissue geometries. Once the geometry has been 107 digitised, the 3D models generated are then discretised or 'meshed' to enable numerical calculation 108 (Figure 2). Clinically relevant loads and material properties can be then input to the model, and lastly 109 the model can be solved (Figure 3). There are many different software packages available for each of 110 these steps, and no standardised combination used within the published research.

The geometry of the foot and ankle is highly complex; hence, many simplifications are made at various stages of the modelling process. This review aims to demonstrate the processes required to produce a reproducible, standardised foot or ankle model for use in clinical applications (Figure 4). In recent years, the uptake of *in silico* methods has increased vastly in foot and ankle research, hence it is important that these models are appropriately addressing their research questions and that the biomechanics community work together to ensure clinically relevant and consistent data.

117 2 Model Generation

The processes involved in model generation are key to an accurate simulation being possible, ensuring 118 119 geometries are correctly represented. MRI or CT have been used separately or in combination to 120 generate the 3D volume from which finite element models are produced. Bone is more appropriately 121 modelled by CT, and cartilage from MRI, due to them being the respective gold standards for obtaining 122 geometry. The optimal model composition would therefore be bone extracted from CT, and cartilage 123 from MRI, however this has associated costs for additional scanner time for per research participant. 124 Multimodal image coregistration CT can be automated and carried out in licensed software such as 125 Matlab (The Math Works Inc.) or freeware such as ImageJ (NIH). Scanner hardware can be 126 programmed so that the image resolutions are similar for the two image modalities, however, some 127 postprocessing would still be involved, meaning there would also be additional researcher time 128 required.

There have been no studies published contrasting models generated entirely from CT or MRI on the same foot and ankle geometry to understand as to what extent this influences model outputs. Other imaging parameters, such as slice thickness, slice gap, and voxel size, will also influence model accuracy. However, this information is rarely cited in literature and is not standardised due to different scanners set-ups; this is a current knowledge gap in the literature which needs to be filled. A recent literature review by Barkaoui *et al.* explored several different imaging modalities used to create orthopaedic finite element model and emphasised that each modality has its strengths and

136 weaknesses [68]. MRI scans are much more suited to representing soft tissues as these are rarely 137 visible within CT scans, but CT is more suited to represent hard tissues such as bone. In relation to the 138 foot-ankle complex they discuss an unusual study by Wong et al. [69] who created an MRI-based FE 139 model to look at talus and calcaneus impact fracture risk; due to the modality chosen the authors 140 could not represent the heterogeneous material properties of the bones so they simplified this to 141 homogeneous orthotropic properties for the cortical and trabecular regions. Interestingly the model 142 was successfully validated against experimental data from a cadaveric experiment, though the 143 cadaveric results had large variability.

144 Conversely, models generated from CT need to make assumptions about the soft tissue elements of a 145 model, for example, utilising a uniform cartilage thickness [44, 45, 70] or excluding cartilage from the 146 model [10, 12, 17, 23, 48, 49, 71]. From MRI, bone boundaries are less clearly defined, but subject 147 specific cartilage segmentations can be carried out for a more accurate representation of the 148 geometry. This soft tissue definition can be taken advantage of, with some models including 149 segmentations of ligaments [57] and muscles [50, 56]. The ligaments are commonly simplified to linear 150 spring elements, trusses or excluded from models [15, 28, 37, 41, 51, 72], while muscles are usually 151 accounted for in the forces applied in the models, and their absence noted as a limitation of the 152 methodology. This is deemed appropriate unless the aim of the model is to consider the functions of the muscle [50]. 153

154 2.1 Discretisation

FE models discretise the structure into small elements with simple shapes. In orthopaedics, this complex geometry is commonly discretised into tetrahedral or hexahedral elements which have robust meshing algorithms. These can be described as first order, or second order, which relates to the number of nodes present in an element; as the nodes are the locations at which the partial differential equations are solved, an increased number of nodes would suggest an increased model accuracy. There is a limit to this, and this is known as the point at which the mesh converges; it is

important to show that the meshing parameters do not influence the model outputs, while keepingthe computational expense as low as possible.

One mesh convergence of a human foot model was found in the literature [73]; the study considered 163 164 five mesh densities, using the same element types, under different foot loading conditions. The 165 findings showed a sensitivity of the mesh convergence to the loading conditions; however, it was 166 suggested a 2.5 mm edge length may be appropriate for most models. This falls within the region of 167 studies using converged global mesh densities, where target edge lengths have ranged from the region 168 of 1 to 1.5 mm [37, 39, 41], to 3 mm [48] or 4 mm [18, 32]. On the face of it an element size of 2.5 mm 169 might be considered far too large to get accurate results considering the dimensions of different 170 tissues within the foot, but when considering discretisation it is essential to always consider what 171 geometry is being represented. In this study the authors were interested in the contact stress 172 underneath the toes, and the inner geometry of the structures within the foot were greatly simplified 173 enabling a relatively large element size to be used. So although the literature gives a general idea of 174 commonly used mesh sizes, but it is important to note that the optimal mesh size to use will always 175 depend on the particular model, the research question, and the output parameter of interest.

176 The variability based on the different loading conditions highlights the importance of assessing for a 177 converged mesh, however, very few studies [15, 25] detail if a mesh convergence has been carried 178 out. Studies tend to only report element type, with some giving total number of elements or nodes 179 [62, 63, 71, 74], or element edge lengths. In studies that detail the total number of nodes or elements, 180 it is unclear if the element size is constant throughout the volume, or whether the model uses different 181 mesh densities in different regions. For example, higher mesh densities where articulations occur [19, 182 20, 56], in thinner regions to avoid the loss of morphology [50], or in regions of interest for outputs 183 [25, 31, 43]. If it is the latter then knowing the overall number of elements is insufficient information 184 to define the mesh.

Relatively few studies report the additional mesh qualities of aspect ratios, internal angles, and Jacobians [12, 32, 56]. A perfectly shaped tetrahedral element would have an aspect ratio of 1, a Jacobian of 1 and internal angles that do not deviate greatly from 60 degrees. There are other factors to consider in mesh quality checks such as skewness that do not seem to have been reported for any foot and ankle models. Finite element models with large aspect ratios, or negative Jacobians may not produce accurate results and can lead to localised outliers in the results data, and consequently mesh quality checks should be considered when generating a model for clinical use.

192 2.2 Material Properties

The level of detail required from material properties depends on the model application; simplifications are common due to the complex nature of biological tissues. Where there are unknowns, or assumptions made, sensitivity analyses should be carried out to ensure these do not influence the outcomes of studies. There have been examples in foot and ankle literature of sensitivity studies regarding cartilage thickness [51], frictional properties [19, 20, 29], loading conditions [60, 64], and material properties [12, 33, 34, 47, 59, 61, 63]. Other studies considering osteochondral defects have also checked sensitivity to defect size [35, 40].

200 The sensitivity to material properties is key, as properties are often simplified due to the lack of raw 201 data on mechanical properties. Properties for the bone and cartilage are often simplified to linear 202 elastic models, with hyper-elastic models sometimes used for the soft tissues. When simplified to 203 homogenous isotropic materials, the properties of bone (Table 1) often assume an elastic modulus (E) of 7,300 MPa. This value originates from a weighted average of the cortical and trabecular elastic 204 205 moduli in a healthy ankle [75]. Some studies have considered treating all bone as cortical bone [35, 206 53], while others have used significantly higher unreferenced values [14]. One study has compared 207 the influence of four different elastic moduli (7,300 MPa, 14,600 MPa, 21,900 MPa, and 29,200 MPa) 208 on a foot and ankle model [59], the study found increased elastic moduli could lead to an 209 underestimation of bone stresses and strains.

When modelling cortical and trabecular bone as separate linear elastic homogenous isotropic materials, there is less agreement on the properties to be used. The most common cortical bone elastic modulus is 17,000 MPa, which has been used in combination with trabecular values ranging from 400 to 700 MPa. However, these models assume that all cortical and trabecular bone has one constant material property, which is a significant simplification of the real tissue [76].

215 Bone material models can be further improved by considering the anisotropic nature of bone [57], or 216 modelling more precisely the inhomogeneity. Hounsfield Unit (HU) based properties from CT are likely 217 to provide the most accurate representation of bone across the model, provided they are correctly 218 calibrated. Heterogenous material assignment has been applied in some studies, where bone is 219 modelled with subject specific mechanical properties [15, 19, 20, 29, 32, 33, 39, 51, 72]. This, however, 220 increases the model complexity and for those models not considering bone outputs this may an 221 unnecessary expense, but if a patient is osteoporotic or the focus of the study relates directly to the 222 bone such as fracture healing then it is crucial that the distribution of mechanical properties be 223 accurately assigned.

Cartilage, when included in a model, is simplified in its properties (Table 2); either linear elastic, or hyper-elastic properties are used, however these both still assume isotropic behaviour. Articular cartilage is both orthotropic [77] and biphasic [78] in nature. The biphasic nature of cartilage has previously been investigated in representative 2D [79] or 3D [80] FE models, not macroscale joint models; these characteristics would be extremely complex to translate to a whole foot or ankle model.

There are a considerable number of models of the natural foot and ankle that do not include additional structures to represent the cartilage [10, 12, 17, 22, 23, 48, 49, 51, 53, 74], instead frictionless contact definitions between bony segments are used to represent the lubricated nature of the articular cartilage surfaces during loading [17]. This simplification may be appropriate in some modelling scenarios where the outputs of interest are in the soft tissues or ligamentous structures.

234 When cartilage is modelled as a linear elastic material, both the elastic modulus (E) and Poisson's ratio 235 (v) vary. The elastic modulus represents by how much a material will deform in response to a particular 236 load, and the Poisson's ratio represents by how much a material volume compresses in response to 237 load, where a material with a Poisson's ratio of 0.5 is completely incompressible and if it is -1 then 238 the material has no resistance to volume change. These values independently influence the 239 mechanical behaviour of the cartilage and in turn impact the model results. With the exception of one 240 study [37] cartilage has been modelled with a significantly lower elastic modulus than the bone. The 241 Poisson's ratios used tend to fall within a range of 0.4 to 0.49 which shows that cartilage does not 242 undergo much volume change under load but it can readily change shape enabling it to conform to 243 the articular surfaces while providing impact resistance. This is largely accepted as appropriate for 244 modelling cartilage in the foot and ankle; however, when considering cartilage outputs such as contact 245 pressures a hyper-elastic material model would be more appropriate as it can replicate the time-246 dependent properties of the tissue deformation under load. There is no agreement in literature on 247 the foot and ankle as to which model is the most appropriate for this application, with Yeoh, Neo-248 Hookean, Mooney-Rivlin and Ogden all used. In a 2D simulation carried out on the knee [81], Neo-249 Hookean and Mooney-Rivlin models were compared; through validation against a mathematical 250 model it was seen that non-linear Neo-Hookean provided the most appropriate model for 251 characterising cartilage behaviour.

Ligaments are commonly modelled as trusses with a cross sectional area, with all ligaments modelled with the same Elastic Modulus; 260MPa is used most commonly [14, 21, 23, 48, 49, 54, 55, 58, 59]; however, 20MPa [40] and 350 MPa [74] have also been reported in literature. For added complexity some studies have given each ligament its own Elastic Modulus, these have used a variety of ranges including 7 to 18.44 MPa [36], 100 to 320 MPa [53] and 99.5 to 512 MPa [1, 11].

Another method of modelling ligaments is using linear spring elements; these are defined with stiffness values (Table 3). Some of the stiffness values have been derived from mechanical test data,

but for ligaments with no associated mechanical testing data a stiffness of 70 N/mm has been assumed. There is some variation between studies with different sources of original values [18], but it is not possible to identify the impact of this variation on the model outputs due to other differences in the study designs.

In the models that include soft tissue structures, these tend to be the focus of the outputs, hence efforts are made to accurately represent the hyper-elastic nature of plantar tissues. The two hyperelastic models used were Ogden [11, 22, 46, 82] and Second Order Polynomial [21, 54, 56, 63, 64, 74]. There are reports that simplify the soft tissues properties to a homogenous isotropic linear elastic material [14, 55, 83], however, this simplification might influence any plantar contact pressure outputs should this be a focus of the study.

269 2.3 Contact Definitions

270 In models composed of more than one part, the contact definitions are key to how the parts interact 271 with one another. The interaction between bone and cartilage is most frequently defined using tie 272 constraints, which means that there is no relative movement between the two parts treating them as 273 one entity. As previously mentioned, there are numerous foot models that do not require these tie 274 constraints as they do not include cartilage components. The tangential contact properties they define 275 between bone to reproduce articular motion are also required between articular cartilage surfaces. 276 These are largely defined as frictionless [38, 52, 54, 55, 58, 63, 74, 84], or with a low coefficient of 277 friction such as 0.001 [40], 0.01 [2, 18, 30, 35, 36, 44, 47], or 0.02 [12]. Higher coefficients of friction 278 (0.1) have also been assumed in some models [43, 57], which is still within the bounds of coefficients 279 of friction found experimentally [85].

Some models have also included normal contact behaviours, which have predominantly been defined as "hard" [15, 38, 41, 51, 52] using either the Penalty or Augmented Lagrange algorithm. Some models also use a non-linear normal contact definition [33, 47, 49]. These contacts tend to be defined using a

surface-to-surface discretisation rather than node-to-surface, as it produces lower errors for contact
 pressures, however, it is more computationally expensive.

285 2.4 Loading and Boundary Conditions

Once the contact is defined to allow for relative movement at articulating regions, the loading and boundary conditions must be appropriately defined to simulate motion. Correctly representing the loading conditions of the foot and ankle is a complex task due to the number of joints and articulations to consider with the force distribution [86].

These loading and boundary conditions can be used to simulate both static and dynamic motion; examples include replicating surgical procedures [41] and experimental setups [8, 12, 25, 43, 64], such as anterior drawer tests [34, 57], or simulating biomechanical data [2, 11, 15, 21, 32, 51-55, 58, 82, 83]. The application of biomechanical data to models has been both dynamic and simplified to quasistatic at points in the gait cycle depending on the outputs of interest.

295 This data is either scaled to represent a subject specific bodyweight (BW), or an average BW, which 296 tends to be set at 600 N [1, 16, 35, 36, 38, 47]. A proportion of this BW is used in static models 297 simulating neutral standing. These have been done with various degrees of simplifications and 298 assumptions depending on the model setup. For example, in models that include soft tissues, and a 299 flat surface to represent the ground, 50% BW might be applied to the ground which has a contact 300 defined with the plantar surface [14, 23]. In many of these cases, an opposite load is applied through 301 the Achilles to represent the Achilles tendon force [33, 62-64, 74]. Other loading conditions considered 302 have been single leg standing, where 100% BW is applied [36, 71], up to 320% BW [44], and 520% BW 303 [29, 72], which was selected to represent the peak load experienced in stance phase of gait [29]. In all 304 cases, some sort of constraint must be applied to the model to stop free body movement.

305 Some models, loaded proximally, have also taken into consideration that the load transfer through 306 the tibia, and through the fibula is not equal. For example, one study simulating a participant 307 bodyweight of 98 kg used the assumption that 84.3 % BW is transferred through the tibial column, and 15.7% through the fibula. Giving a tibial loading of 810.44 N, and a load of 150.94 N through the
fibula [37]. A second study used slightly different proportions, with 93.59 %BW transferred through
the tibia, and 6.41 %BW transferred through the fibula [40]. This is not a split that could be accounted
for in the models loaded distally.

312 2.5 Solving

The underlying numerical calculations performed by the simulation software, whether an implicit [31, 43, 57] or explicit [12, 46, 53, 83] solver is used, is another important difference in models of the foot and ankle, but surprisingly it is not frequently reported which is another barrier to reproducibility. These two solver types calculate the state of the model in different ways, taking time into consideration differently. Therefore, the two different solvers may not give the same solution to a simulation, require different verification, and they are appropriate for different strain rates.

Simulations of the foot and ankle have been carried out using dynamic, static, and quasi-static methods, depending on the application and the required level of complexity. For example, those models considering impact [8, 9] require dynamic simulations; however, gait has been considered using both quasi-static and dynamic methods depending on whether the whole gait cycle is simulated or independent events of stance phase.

324 3 Results analysis (post-processing)

Once the simulation is carried out, appropriate postprocessing and interpretation of results is a vital next step enabling clinical assertions to be made from models. The relevant output depends on the question raised, and the tissue of interest. Despite models often including all structures of the foot and ankle, results might only consider one specific region, for example the plantar tissues, or a specific bony region. These regions can have one or more output reported for them, however, the justification for the choice of output is not always explicitly clear with how it relates to the research question. The postprocessing of results is key in delivering clinically relevant outputs; clear examples of outputs chosen due to their application are micromotions when considering joint fixations [19], bone remodelling in total ankle replacements [72], or plantar pressures when looking at shoe or insole designs [62, 63]. The interaction with a device, and understanding of potential failure mechanisms due to this, give rise to obvious postprocessing choices. However, this is not always obvious, and studies may consider an output based on the ability to carry out validation [64] with a more tenuous clinical significance.

338 Understanding the clinical relevance of specific model outputs is a key starting point in the 339 postprocessing of results, as FE software has the capacity to potentially produce hundreds of output 340 types for a mechanical model. In orthopaedics stresses, strains, and contact pressures are common 341 outputs of interest which would all have clinical relevance. These, however, are generic terms, and 342 each will have types (e.g. principal stresses), as well as directional components, which will have 343 differing relationship with tissue health. Von Mises Stress is the default stress output in most FE solvers 344 and is consequently frequently used to consider orthopaedic model outputs, without any comment 345 on whether this is appropriate. Von Mises Stress is a good indicator of stress distribution, and stress 346 concentration location. However, it does not indicate whether stresses are occurring in compression, 347 tension, or shear, which is highly relevant to orthopaedics as bone has high compressive strength but 348 poor tensile and shear strengths. Furthermore when modelling bone as a heterogeneous material, the 349 von Mises results will be dependent on the modulus assignment and so strain-based outputs are more 350 clinically informative.

The FE method is best implemented when there is a clear failure mode, and therefore stresses or strains – once validated – can be directly contrasted with this, to suggest the likelihood of failure under a certain condition. For example, excessive strains in ligaments might highlight the potential for overstretching or rupture. Or in bone, changes in stresses and strains leading to bone remodelling can

be implemented using bone adaptation laws which can highlight potential changes in bone mass aftertreatment[15, 72].

The applicability of these results is partially governed by the material properties used; for example, contact pressures and their distribution may not be appropriate in regions where linear elastic material properties have been used. This is because this material property influences the contact mechanics, which directly relates to the contact pressures. Careful consideration must be taken when defining material properties that are appropriate for the purpose of the model. Therefore, it is important that the research question is defined, and failure mechanism considered, at the beginning of the modelling process.

364 4 Validation

Care must be taken in models with clinical implications that input parameters accurately represent the model and simulation [87], to ensure that the outputs of a model are meaningful. Alongside this it is pertinent that the model is validated, to draw any conclusions, or make any predictions from its outputs. Validation is the process of determining the degree to which the model is an accurate representation of the real world from the perspective of the intended use for the model [88]. Once a validation is successfully achieved, there will be increased confidence in the interpretation and value of the results.

Validation against previously published data is the most common technique used in foot and ankle
 models (Figure 5), while assessing against a gold standard experimental technique is the preferred
 validation method; model-model validation [59] is also possible, but less frequently used.

The importance of validation is much reported in literature [89-91], however, some foot and ankle studies do not report validation methods [13, 34, 35, 41, 44, 65, 66, 70, 92], appear not to be validated, or state the lack of validation is a limitation of the model [2, 15, 17, 19, 26, 31, 37, 72, 74, 82, 93]. Models where this is the case tend to only be able to consider the relative change between cases using

the same methodology, and not absolute values. They are therefore still valuable, but not to clinicalpractice.

In those that do carry out *in vivo* or *in vitro* validation, this may be the main objective of the model generation [45], or be possible due to the data collected for input parameters; such as joint angles [9], loading [8] or GRF [58]. The standard for validation is to carry this out for the primary model output [90], such as; plantar pressures [46, 56, 94], peak strains [10, 25] or joint contact pressures [45, 71]. Of the studies which have been validated experimentally they can be split into five main groups:

High experimental variability: where the FE results match the experimental data, but the
 experimental data is highly variable (particularly common with cadaver experiments) so it is
 hard to know for sure if the FE results and trends are representative [8, 43, 59, 95].

- 389
 2. Large difference between model and experiment: where the difference between the model
 390 and the experiment, for some or all data, is high (>10%) [12, 28, 71].
- 391 3. Trends validated but inaccurate magnitude: where the model shows the same trends but the
 392 values output are very different to the experimental data [64, 94].
- 393 4. Insufficient experiment sample size: where the model and the experiment matches, but the
 394 variability in the experimental data is uncertain [45].
- 395 5. True match between experiment and model data: where the experimental data has been
 396 acquired robustly and the FE results closely match [25, 40, 42, 57].

397 Many of the above validated models are still useful and are able to answer clinical questions but it is398 important that studies are open about the limitations behind their model validation.

Validations carried out against literature will be limited to studies considering the primary output; or may guide users to select a primary output based on what can be validated, rather than the research question. The simulation is also limited to replicating the model setup used in the previously reported study, as model parameters such as loading conditions and material properties should be kept in common for the purpose of validation. After the model is validated, it is then possible to ascertain the sensitivity to any parameter changed. For example, parametric tests could be used to examine the
biomechanical effects of different sizes, shapes, and positions of osteochondral defects of the talus,
which may assist our surgical decision-making as well as provide guidance on the likely natural history
without intervention.

These validated models then have the capacity to accelerate the research area, without the use of new resources each iteration, due to one model having the potential to simulate a multitude of scenarios.

411 5 Clinical relevance

412 Of the studies explored in this review, few have led to changes in clinical practice. Viceconti et al. suggested some basic requirements for a clinically useful numerical model [89]: 1) clear rationale 413 414 behind why a numerical model is needed, 2) evidence that the model has been verified, 3) clinically 415 relevant input parameters, 4) sensitivity analysis to understand how uncertainty (patient and other 416 variability) impacts on the model, 5) experimental validation of the data, 6) risk-benefit analysis so 417 clinicians can quantitively assess the risk involved in using the model. None of the papers examined in 418 this literature review met all of these requirements, but also many did not seek to answer a direct 419 clinical question and instead were focused on the methodology of the model development [45, 94, 420 95] with a promise of later application. This approach can be fruitful but relies upon work continuing 421 into the long term, and if a model were to be developed for general use it would need to be sufficiently 422 flexible and accessible to enable a variety of clinical questions to be answered.

The Open Knee model [96] is an example of an orthopaedic FE model that has allowed for clinical translation; this open-source model has allowed investigators outside of the developers to utilise the model in research relating to the biomechanics and tissue structures of the knee joint. This has not only expedited the research capacity in the field but has standardised some aspects of model generation. An equivalent model, to the best of the authors' knowledge, is not available for the whole

foot or ankle; therefore, the authors propose a similar strategy is required for this joint to improve translation into clinical practice. This could be either a single patient specific model, or several models to create an in-silico population. Alongside this a general template or checklist on good practice when creating a model of the ankle could improve the clinical usefulness of models; but as evidenced by Viceconti's paper, such recommendations are not always followed. Our view is that provision of standard materials that make it easier to create good quality models of the ankle, alongside guidelines, is the way forward.

435 6 Conclusion

The value of foot and ankle modelling is clear in clinical practice; however, to date the translation has not been as successful as various other orthopaedic or cardiovascular systems. Finite element models of the foot and ankle are becoming increasingly prevalent, however, the lack of standardisation and clear reporting in the field hinders its success and wider application. Therefore, a conclusion of this review relates to the improvement of these aspects to allow for better clinical translation.

This is highly challenging, due to the complexity of the foot and ankle; hence, models tend to be purpose built with simplifications to elements of lesser interest in the model. Therefore, often models may not be appropriate for processing results relating to the bone or cartilage as their complex material properties are often simplified, or not modelled – as is sometimes the case with cartilage in whole foot models. These simplifications and their potential impact on results are often brushed over, however, are key in understanding if a model is robust and can therefore provide inciteful, clinically relevant outcomes.

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694 Tables

695Table 1 Summary of bone properties reported for foot and ankle models

	E (MPa)		v		References
	7,300		0.3		[1, 11, 21, 22, 28,
					54, 55, 62-64, 74,
					82, 83]
Homogenous	7,000		0.3		[58]
isotropic	17,000		0.3		[35, 53]
	10,000		0.3		[23, 48, 49]
	29,200		0.3		[14]
	Cortical	Trabecular			
	19,100	1,000	0.3		[37]
	19,000	531	0.3		[8]
	17,000	700	0.3		[17, 56, 71]
Cortical and	17,000 500		0.3		[31]
Trabecular	17,000	477	0.3		[18]
	17,000	400	0.3		[12, 40]
	13,000	1,000	0.3		[41]
	12,100	530	0.3		[36]
	7300	1100	0.3		[60]
Isotropic Cortical, CT	Cortical	Trabecular			1
greyscale Trabecular	19,000		0.3		[29, 33]
	Cortical	Trabecular	Cortical	Trabecular	

Anisotropic cortical	E1=	E2=	450	v 12=0.31	0.3	[43]
bone	17,500			v13=0.43		G13= 3,500MPa
Isotropic trabecular	E3=11,5	500				
bone						
CT Greyscale Based						[15, 19, 20, 32, 39,
						51]
Cortical, cancellous	3790 · p) ³				[72]
and Interface						
densities (p)						

697 Table 2 Summary of cartilage properties reported for foot and ankle models

	E (MPa)	V	References
Linear Elastic	0.7	0.49	[8, 34, 84]
	0.83	0.49	[36]
	1	0.4	[2, 14, 21, 28, 54-56, 62-64,
			82]
	10	0.4	[11, 29, 33, 56]
	10	0.45	[40]
	12	0.4	[18]
	12	0.42	[1, 35, 44, 45]
	12	0.45	[52]
	50	0.1	[58]
	1230	0.42	[37]
Hyper Elastic	Yeoh: C1=23.42MPa, 5.28MPa, C4=29.94M		[43]

D1=25.60MPa, D2=215.14MPa D3=215.89MPa, D4=254.18MPa and D5= 31.66MPa.	
Neo-Hookean: 0.49, C10 = E/(4(1+n))	[83]
Mooney-Rivlin: C01=0.41 MPa and C10=4.3 MPa	L [60]
Ogden: μ=2.43, α=12.45, D=0.176	[30]

699 Table 3 Spring stiffness, k (N/mm) reported in literature where ligaments were modelled as

linear spring elements

	[18]	[33]	[60]	[95]
Anterior talofibular	142		90	90
Anterior tibiofibular	78	90	78	90 (proximal), 70 (distal)
Anterior tibiotalar	123	90	70	70
Calcaneofibular	70	70	70	70
Interosseous 1-4	400	400	400	400
Interosseous talocalcaneal		70	70	70
Lateral talocalcaneal	70	70	70	70
Medial talocalcaneal	70	70	70	70
Posterior talocalcaneal	70	70	70	70
Posterior talofibular	82	70	70	70
Posterior tibiofibular	101	90	101	90 (proximal), 101 (distal)
Posterior tibiotalar	60	80	80	80
Tibiocalcaneal	122	122	122	122

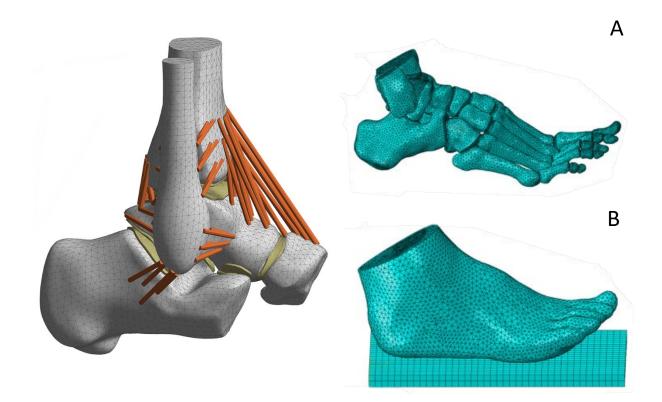


Figure 1 FE model of the bones of the ankle with 3D renderings of 2D truss elements used for ligaments (left) [1], and of the whole foot (right) adapted from Wang et al. where A) shows the underlying bony structures of the foot and ankle modelled, and B) shows the encapsulated tissues and rigid plate included in the simulation[2].

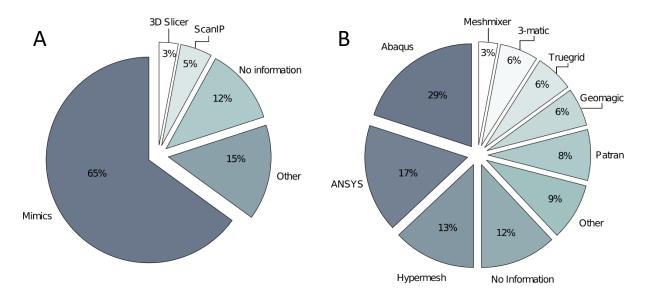
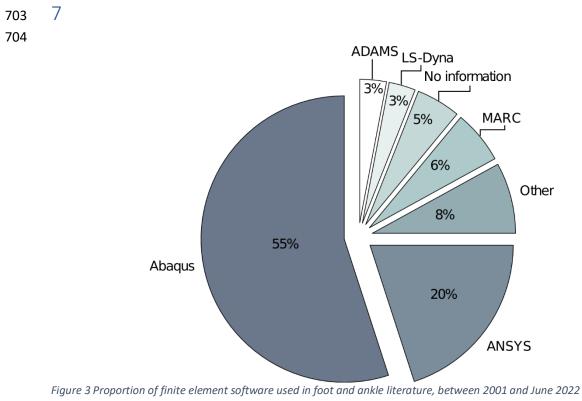
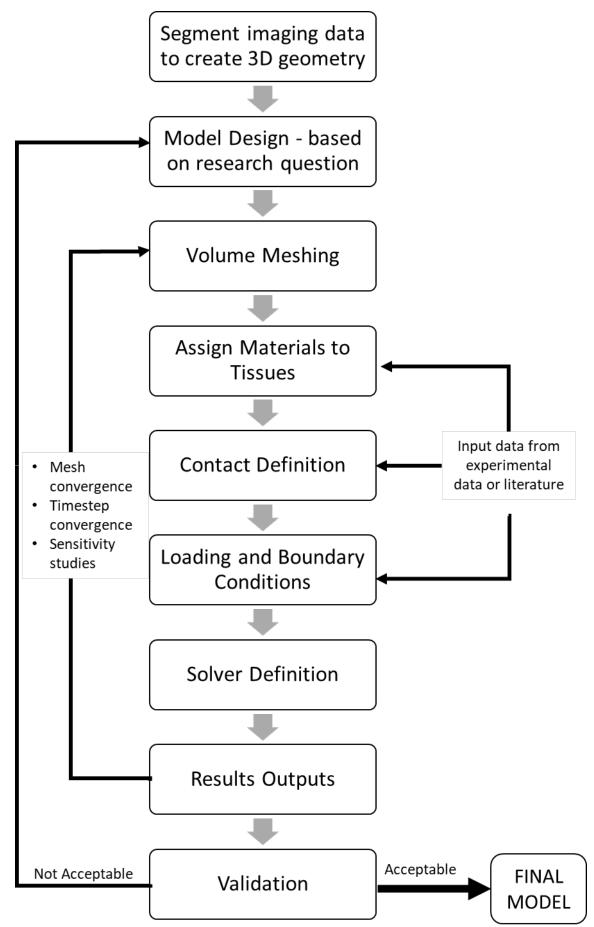


Figure 2 Proportion of software used for A) segmentation and B) meshing based on analysis of foot and ankle FE literature, between 2001 and June 2022





706Figure 4 Flowchart of processes to generate a validated finite element model

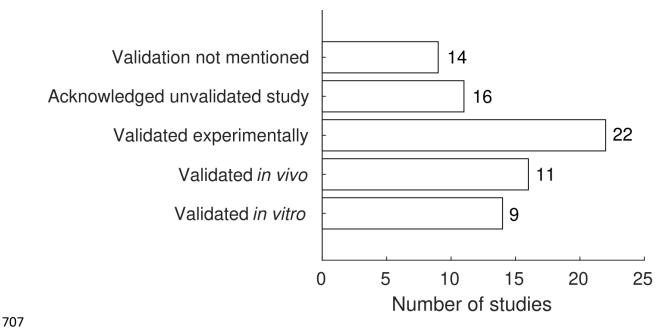


Figure 5 Number of studies in literature reporting methods of validating foot and ankle models