

# **A review of foot finite element modelling for pressure ulcer prevention in bedrest: current perspectives and future recommendations.**

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## Highlights

- Nine FE foot models for pressure ulcer prevention in bedrest exist, yet all produce conflicting results.
- It is difficult to draw clear clinical conclusions due to the methodological limitations.
- Internal soft tissue strains are influenced by foot posture, slope and stiffness of the mattress.
- The limited number of studies emphasise the need for further research in order to provide valuable clinical conclusions.
- Recommendations for future FEA of the foot in bedrest are presented.

## Abstract

Pressure ulcers (PUs) are a major public health challenge, having a significant impact on healthcare service and patient quality of life. Computational biomechanical modelling has enhanced PU research by facilitating the investigation of pressure responses in subcutaneous tissue and skeletal muscle. Extensive work has been undertaken on PUs on patients in the seated posture, but research into heel ulcers has been relatively neglected. The aim of this review was to address the key challenges that exist in developing an effective FE foot model for PU prevention and the confusion surrounding the wide range of outputs reported. Nine FE foot studies investigating heel ulcers in bedrest were identified and reviewed. Six studies modelled the posterior part of the heel, two included the calf and foot, and one modelled the whole body. Due to the complexity of the foot anatomy, all studies involved simplification or assumptions regarding parts of the foot structure, boundary conditions and material parameters. Simulations aimed to understand better the stresses and strains exhibited in the heel soft tissues of the healthy foot. The biomechanical properties of soft tissue derived from experimental measurements are critical for developing a realistic model and consequently guiding clinical decisions. Yet, little to no validation was reported in each of the studies. If FE models are to address future research questions and clinical applications, then sound verification and validation of these models is required to ensure accurate conclusions and prediction of patient outcomes. Recommendations and considerations for future FE studies are therefore proposed.

## Keywords

Biomechanics; Decubitus; Finite element modelling; Pressure ulcers; Prevention

## 1. Introduction

Sustained mechanical loading of the skin and underlying soft tissues can lead to soft tissue damage or ulceration. Both normal pressure and frictional shear forces applied to the skin can cause deformation and injury to the soft tissues, especially over bony prominences. Whilst this is commonly described as a pressure ulcer (PU), any type of loading apart from a uniform hydrostatic pressure will cause shear deformation of the tissue and hence potentially lead to injury.

In the United Kingdom, the cost of treating a PU varies from £1,214 to £14,108, with the overall daily costs in the region of £1.4 million [1,2]. Global PU prevalence rates vary considerably between different geographic and clinical settings, with the UK reported to have the highest point prevalence of 26.70% in a recent systematic review [3]. PU management is therefore a relevant problem that has still not been fully addressed, whereby the development of new intervention strategies to manage PU prevention is required.

The aetiology of PUs is complex with many different intrinsic and extrinsic factors potentially contributing to the onset and development of a PU. Although it is known that sustained mechanical loading is the primary cause of PUs, the aetiology is also connected with a variety of biomechanical, physiological, and biochemical processes at the cellular and tissue level [4]. The underlying damage pathways whereby mechanical loading leads to tissue breakdown are poorly understood, although it is believed that ischemia, reperfusion, impaired lymphatic drainage and sustained deformation of cells may play a pivotal role [5,6]. To understand the aetiology of PUs and potentially improve the management and prevention of PUs, healthcare professionals should be able to predict whether or not a certain state of internal mechanical loading (such as tissue deformations and forces per unit area of tissue) would lead to localised irreversible cell damage [7,8].

The heel is one of the two most common sites for PUs, experiencing some of the most severe pressure injuries [9,10]. It is considered a particularly vulnerable area due to its anatomy, disease burden, co-morbid conditions, and the ageing process [11]. Current clinical practice to help prevent heel ulcers involves either the repositioning of the patient, and/or redistributing the pressure using a support surface such as overlays, heel boots or mattress systems. Whilst this offers tissue viability nurses general guidance in dealing with PUs, the mechanics of pressure injury and its prevention are still poorly understood, and such devices are not always effective in all patients.

Finite element (FE) modelling is one approach that has the potential to inform clinical practice and prevent heel ulcers either as a tool for preclinical testing of support interfaces and/or identifying anatomical risk factors. Although it considers only mechanical loading and ignores the many other factors that may be involved in PU formation, it does offer the possibility of exploring the effect of mechanical factors in isolation, which is difficult in clinical studies. Such an approach requires that we assume a link between mechanical loading and injury, but we do not know exactly what this mechanism is or the precise injury thresholds, which is a key limitation of this method.

FE modelling is a conventional computational technique for estimating internal stress, strain and deformation under load, and can be used to predict damage where these exceed appropriate criteria. Whilst not routinely used for PU management, medical imaging modalities such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) can provide accurate, patient-specific detail of anatomical geometry. Datasets are typically obtained from healthy subjects or cadavers where the volumetric data is segmented into the required regions of interest through manual or automated segmentation. The two-dimensional or three-dimensional model is then meshed and assigned material properties, boundary conditions and external loads (e.g. gravity). Simulations can then be performed in a non-linear FE solver to assess the behaviour of the tissues when interacting with a support surface either in a static or dynamic position.

As PUs are not limited to the heel, a number of studies have used FE analysis to investigate PUs at other anatomical sites, such as the buttock [[12], [13], [14], [15]]. Foot models in a standing posture or dynamic stance are also common, particularly with regards to the development of new insole design or footwear [[16], [17], [18], [19]], as well as foot ulcers from underlying health conditions such as diabetes [20,21]. Yet, similar research regarding heel ulcers for bedridden patients is limited, with only nine studies to date having modelled heel ulcers or diabetic foot ulcers (DFUs) in a supine position [[21], [22], [23], [24], [25], [26], [27], [28], [29]]. It is important to emphasise here that whilst these are both caused by prolonged loading, DFUs include a complex array of underlying complications such as neuropathy, vasculopathy, osteoarticular involvement and infection. A PU, on the other hand, is defined as a localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear [30]. Both PUs and DFUs are included in this review to highlight the differences between the healthy and diabetic foot, as previous research has shown that atypical foot anatomies are more susceptible to heel ulcers than the healthy foot [21].

This review has been written primarily for engineers and those interested in FE modelling but is in a format which will hopefully aid understanding for those in the field of PUs who have limited or basic understanding of computational models and engineering principles. Therefore, each section introduces a brief overview of the stages involved in the FE modelling process, before discussing the reviewed studies, the differences in the outputs reported and the effect this potentially has on clinical management.

The aim of modelling is to find out how clinical variables affect the soft tissue strains and therefore the likelihood of injury. We thus aimed to answer the following questions:

- How are the internal soft tissue strains influenced by foot posture?
- How are the internal soft tissue strains influenced by the slope and stiffness of the mattress?
- How are the internal soft tissue strains influenced by the friction co-efficient at the skin–surface interface?

The Discussion section will revisit these clinical questions to evaluate to what extent the models were able to address them, and what adjustments, improvements and additions are needed to answer them more thoroughly.

## **2. Methods**

### **2.1. Search strategy**

The primary aim of the search strategy was to retrieve all original papers on FE analysis of the entire foot, lower leg or posterior part of the heel to assess the validity of the methods used and the outcomes presented. Studies in a standing posture, seated posture or dynamic stance were excluded, along with studies on fracture fixation or broken bones. A formal systematic review was not deemed appropriate due to the limited number of studies in this field.

### **2.2. Selected studies**

The databases searched were Medline, PubMed, Ovid and Scopus. The following search terms were used in combination with the Boolean operators (AND, OR) to enable the identification of all relevant studies: finite element modelling, image-based modelling, computational modelling, heel, foot, lower leg, diabetic foot ulcer, heel ulcer, pressure ulcer, decubitus, supine, bedrest, MRI, CT, FE\* (symbol meaning a ‘wildcard’ character for searching purposes), pressure\* and diabetic\*.

The search was limited to studies with full texts published in English but there were no limitations in terms of publication date or age of participants within the studies. PUs at any stage (i.e. Grade I – IIII) were also included. No attempt was made to search the ‘grey’ literature.

Nine studies met the eligibility criteria for inclusion and were reviewed in this paper (Table 1). These studies specifically modelled the foot or part of the foot and/or lower leg in bedrest with a focus on heel ulcers. Six studies modelled the posterior part of the heel, two models included the calf and foot, and one study modelled the whole body. All studies simulated the healthy foot, with three studies focusing on the implication of deep tissue injury (DTI) and/or diabetes.

Table 1. Studies included in the present review (N = 9) with corresponding information about dataset, foot imaged, number of models, number of participants (Pt) and their demographics, geometry and study focus, foot orientation and weight of lower leg and foot (where DTI = deep tissue injury, BW = body weight and \* foot orientations are in plantar flexion and not abduction/adduction).

**Table 1: Studies included in the present review (N=9) with corresponding information about dataset, foot imaged, number of models, number of participants (Pt) and their demographics, geometry and study focus, foot orientation and weight of lower leg and foot (where DTI = deep tissue injury, BW = body weight and \*foot orientations are in plantar flexion and not abduction/adduction).**

Study	Dataset	Foot	No of Models	Gender	Pt	Age (yrs)	Weight (kg)	Height (m)	3D anatomical geometry and study focus	Foot (°)	Lower leg and foot weight/Force	Software
Gefen 2010 [16]	Simplified theoretical model	N/A	1	-	-	-	-	-	Rigid sphere calcaneus and elastic soft tissue layer. Diabetes, edema and dehydration related to heel ulcers	N/A	Foot 1kg [26,27]	-
Sopher et al 2011 [17]	VH - American Cryosections	Left	14	Male	1	38	90	1.80	Posterior portion of heel 65 x 50 mm (W x H) specifically for DTI	60, 90	2% of BW [26,27]	SolidWorks Abaqus
Levy et al 2015 [18]	56 T1- axial MRI slices	Left	9	Male	1	34	90	1.78 ± 0.6 [28]	Posterior part of heel efficacy of dressings for heel PUs	N/A	Downward displacement 4.4 - 5.1 mm	ScanIP FEBio
Luboz et al 2015 [19]	Zygote CAD leg Calcanei from CT data	Right	18	Male	1	-	70	-	Lower leg model Influence of calcanei on heel PU	Neutral	6% of BW [29]	Blender Artisynth
Levy et al 2016 [20]	56 T1- axial MRI slices	Left	20	Male	1	34	90	1.78 ± 0.6 [28]	Posterior part of heel efficacy of dressings for DTI of patients with diabetes	Neutral, 10, 20, 30*	Downward displacement 4.4 - 5.1 mm	ScanIP FEBio
Lee et al 2017 [21]	3D CAD geometry	Both	6	Male	3	20 20 20	63 82 90	1.78 1.84 1.75	Whole body 3D scanning to obtain the silhouette data of the subject with anti-PU mattresses	Neutral	The real BW of each subject	PTC Creo 3D-Doctor Ansys
Friedman et al 2019 [22]	41 T2- axial MRI	Right	30	Male	1	72	95	-	Posterior part of heel with DTI, Injurious tissue loads, angle of mattress	Neutral	1.0 - 2.2% of BW [30] 9.3N and 20.6N	ScanIP FEBio
Zwam et al 2020 [23]	VH - Korean CT	Right	19	Male	1	33	55	1.64	Lower leg model Risk factors for heel PUs	45, 60, 75, 90, 105, 120, 135	6% of BW leg mass 3.36kg	Gibbon Abaqus
Soh et al. 2020 [24]	Simplified 3D CAD geometry	N/A	1	-	-	-	-	-	Cylinder for the lower leg and sphere for the bone. Presence of panniculus carnosus muscle. PU and dressings	N/A	20N of one foot (2kg)	SolidWorks Abaqus

### 3. Results

#### 3.1. Imaging modalities, datasets, and FE geometry

High-resolution MRI and CT images are used to reconstruct geometrically accurate 3D foot models of individual subjects which can provide valuable information on the tissue deformation and damage caused by external loading. MRI provides good spatial resolution (the ability to distinguish two separate structures an arbitrarily small distance from each other) and better contrast resolution (the ability to distinguish between two arbitrarily similar but not identical tissues) for soft tissues than CT scans, and can generate cross-sectional images in any plane [31].

Each image within the MRI or CT scan is called a slice, which stacked together forms a volume (or volumetric data). This stack can be translated into a mesh, which subdivides the stack into domains called elements. These elements can be tetrahedral or hexahedral and linear or quadratic shape functions can be used, resulting in elements with straight or curved edges respectively. The smaller the elements, the more accurate the FE model, but this will also increase the computational time (as a set of equations are solved over each element). Fig. 1 shows an example of an individual sagittal CT slice of the foot, through to a finely meshed 3D FE model.

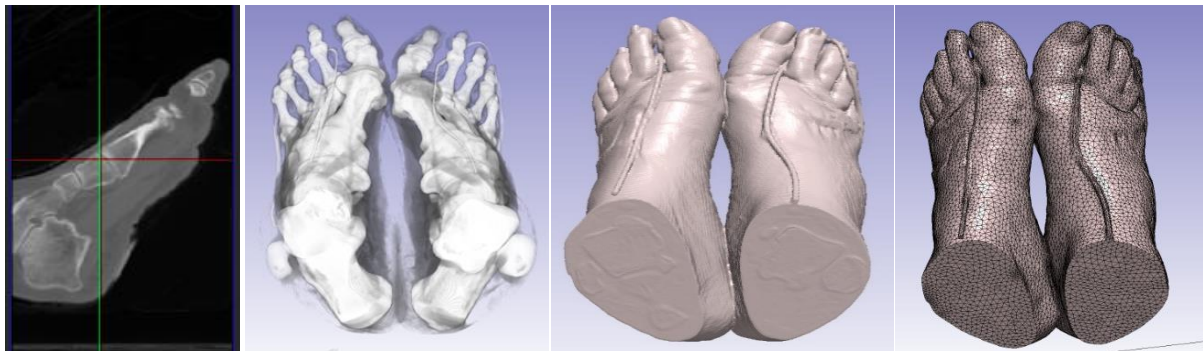


Fig. 1. From left to right - Individual 3D slice from Visible Human CT dataset [31], volumetric data, segmented skin model and a mesh containing tetrahedral elements.

Of the nine studies reviewed, three studies involved MRI data, but with two types of sequences: T1-weighted (typically used to investigate normal anatomical details) and T2-weighted (more commonly used to investigate tissue edema). Both studies by Levy et al. used existing T1-weighted axial MRI data from Tenenbaum et al. where the left feet of ten healthy male subjects were scanned with a 1.5 T MRI system [23,25,32]. However, only subject 2 was used to create an FE model and it is not known why this subject was chosen over the other nine subjects. By contrast, Friedman et al. used a T2-weighted axial MRI sequence to scan the right foot of a 72-year-old patient with DTI [27]. Knowing that the mean thickness of the Achilles tendon on the calcaneal tuberosity is  $5.1 \pm 0.63$  mm (range, 3.8–6.9 mm) and the insertional location of the Achilles tendon is inconsistent, the slice thickness of 3 mm used in these studies would result in only one or two slices of MR data. This limited detail is problematic, as it is near impossible to accurately replicate the geometry and location of the Achilles tendon in the FE model and thus assess where the strains are occurring in the soft tissue [33,34].

Due to the ethical issues involved in imaging a patient using ionising radiation, studies involving CT data have typically used a publicly available cadaveric dataset called the Visible Human (VH) Project [35]. Since the original American VH project was launched in 1994, further projects have been developed in Korea (Visible Korean) and China (Chinese Visible Human and Virtual Chinese Human) as found in Table 2 [36].

**Table 2: Whole-body human datasets and demographics (where information is available)**

Whole Body Datasets	Sex (M/F)	Age (yrs)	Weight (kg)	Height (m)	Cause of death	CT slice intervals (mm)	Pixel size (mm)
Visible Human Project [31]	M	38	90	1.80	Lethal injection Suspected heart attack	1.0	0.33
	F	59	-	-		0.33	0.33
Visible Korean [36]	M	33	55	1.64	Leukaemia Stomach cancer	0.2	0.2
	F	26	53	1.60		0.2-1.0	0.1
Chinese Visible Human [37]	M	35	65	1.70	CO Poisoning	0.1-1.0	0.25-
	F	22	54	1.62	Food poisoning	0.25-1.0	0.5
	M	21	66	1.82	-	0.1	0.17
	F	25	57.5	1.62	-	0.25-1.0	-
	F	25	59	1.70	-	0.2	-
Virtual Chinese Human [38]	F	19	46	1.55	Food poisoning	0.2	0.2
	M	24	-	-	Food poisoning	0.2	0.2
	F	0.10	-	-	Foetal distress	0.1	0.1
	M	28	56	1.66	Lethal injection	0.2	0.1
Zygote [39]	M	-	USA 50 <sup>th</sup> percentile	USA 50 <sup>th</sup> percentile	-	-	-

Sopher et al. used the VH anatomical cryosections of the left foot from a 38-year-old American male. The contours of the bone, fat pad and skin were drawn manually for each slice and then lofted into 3D bodies. The FE model was simplified to include only the region of the posterior heel as a 3D 50 mm × 60 mm cube [17]. Zwam et al. used a similar approach for segmenting the contours of the bone, Achilles tendon, and skin before importing into Abaqus to loft into a 3D solid body, however, CT data from the Korean VH project was used for a 33-year-old male [23]. Whilst both the American and Korean males are of a similar age, their weight and height are different (55 kg and 1.64 m compared to 90 kg and 1.80 m respectively). Knowing that the height, body weight and BMI significantly decrease in both sexes between the ages of 70–95 years old and that heel ulcers are predominantly found in older adults, it is important to use a dataset that best represents the population at risk [37].

There is a balance to be made when substituting or combining healthy tissue and bone into a dataset. Friedman et al. ‘filled’ the area where the DTI was present with healthy soft tissue. Whilst this can provide a general idea of where the soft tissue would be present, the subcutaneous tissue is typically damaged and necrotic in patients who present with DTI. Luboz et al. used a similar approach when combining calcaneal CT data with surrounding soft tissue from the Zygote dataset [24]. The calcaneus was removed from the dataset and replaced by subject-specific CT data of calcaneal bone. It is unclear from this study how the CT data of the 18 calcanei were obtained or what CT parameters were used. This data may have been acquired through the Zygote dataset, although it is also possible that it was obtained from a routine clinical CT scan for foot and ankle surgery, perhaps explaining why only the calcaneus was used.

Simplified heel geometry without clinical imaging provides a first-order approximation of the heel but does not reflect the true anatomy. A cylinder is often used to model the lower leg, with the calcaneus modelled as a rigid sphere pressing against a homogeneous linear-elastic layer that represents the soft tissue [21,29]. Surface geometry data can also be obtained using a motion sensor device to reconstruct a 3D CAD model of the body [26].



The complexity of the anatomy and function of the foot requires a wide range of assumptions and simplifications to be made. The reviewed studies included whole lower leg, whole foot and part foot geometry, but it is unclear how complex the foot model needs to be in order to be clinically useful. Deciding which anatomical structures to include in the model is an important question that has yet to be addressed. Geometrically detailed FE models derived from MRI and CT data provide accurate intrinsic anatomy but have the disadvantage of requiring both clinical and biomechanical expertise to develop a model and interpret its results effectively as well as high computational cost. Simplified CAD models offer an alternative approach to developing a heel model, without the need for ethical approval or funding. The advantage of this approach is that it is quick (both to construct and solve), and it can provide estimated results and general insights into biomechanical characteristics as an initial start point. The challenge of defining a simple, yet realistic, biomechanical model which is computationally efficient requires further development and advancement of FE techniques.

### 3.2. Constitutive models and assignment of material properties

Measuring the mechanical properties of soft tissues is complex and there are many potential errors and uncertainties in developing a suitable constitutive model that will describe the behaviour of the material sufficiently [38,39]. The model will never be an exact representation of the behaviour due to the vast number of unknown parameters. Current constitutive models are simplistic and inaccurate, particularly for reliably predicting the behaviour of the foot soft tissues in different circumstances. The material parameters themselves are also difficult to measure accurately and published data is often subject to large and unknown uncertainties.

Due to the intricate structure and unusual properties of soft tissues, it is difficult to accurately simulate their mechanical behaviour. A non-linear material model is therefore used to replicate the relationship between stress and strain (where the materials typically become stiffer the more they are deformed). The incorporation of both non-linearity and time-dependency into a continuum material model represents a highly complex mathematical problem which has led to a range of different approaches in the literature. The most widely used constitutive model for investigating heel PUs are hyperelastic models based on a strain energy density (SED) function.

The simplest hyperelastic model is neo-Hookean where the Young's modulus,  $E$ , and Poisson's ratio,  $\nu$ , must be defined. This model describes a compressible neo-Hookean material and is based on an SED made from the first and third invariants of the left Cauchy-Green deformation tensor. The Mooney-Rivlin model is similarly derived but the coefficient of the first and second invariant term,  $c_1$  and  $c_2$ , along with the bulk modulus,  $k$ , must be defined. The SED function for Ogden differs from the previous two models and is expressed in terms of the principle stretch ratios and the volume ratio  $J$ . The bulk modulus,  $k$ , coefficient and exponent of  $n$ th term  $c [n]$  and  $m [n]$  (where  $n$  can be any positive integer) must be defined. All of these models are isotropic (they have the same properties in all directions), which is arguably inappropriate for tissues like the Achilles tendon which are much stiffer in the longitudinal direction [40].

The material properties for the skin and Achilles tendon have typically been derived from both animal and human data [41,42]. Muscle, ligament and/or fat are often modelled as one homogenous material to define a combined 'soft tissue' layer. Whilst this essentially removes a layer of complexity, this approach does not allow for the stresses or strains at an individual level to be assessed (which is an important consideration for better understanding heel PUs, particularly in the case of DTI). It is obvious that these tissues have very different mechanical properties and so replacing them with a single generic material inevitably leads to substantial inaccuracies. The specific constitutive models used to simulate the mechanical behaviour of the foot tissues and the methods for calculating and assigning their material properties and coefficients are presented in Table 3.

**Table 3 – Strain Energy Density (SED) function, Constitutive model with corresponding material parameters coefficients, where OG = Ogden, NH = Neo-hookean, MR = Mooney Rivlin, LE = isotropic linear elastic, U and L = upper and lower part of support. \*Study by Levy et al 2016 is an extension of the previous study in 2015. Only diabetic material properties given below. Friction at skin – mattress interface except Soh et al where \*friction between bone and soft tissue interface.**

Study	SED function, $W$	Model	Bone/Tissues	Young's modulus E (kPa)	Poisson's ratio $\nu$ (-)	Density (kg/m <sup>3</sup> )	$\alpha$ (-), $D$ (mm <sup>2</sup> /N)	Shear modulus $\mu/G$ (kPa)	Bulk modulus $k$ (kPa)	Friction at interface	Thickness of tissues (mm)
Gefen 2010 [16]	N/A	-	Calcaneus Soft tissue	- 100	- 0.495	- -	- -	- -	- -	- -	- 5
Sopher et al 2011 [17]	$W = \frac{\mu}{\alpha} (\lambda_1^\alpha + \lambda_2^\alpha + \lambda_3^\alpha - 3) + \frac{k}{2} (J - 1)^2$	OG LE OG LE	Skin Calcaneus Fat pad Support	- 7x10 <sup>6</sup> - 10 – 100	0.495 0.3 0.495 0.3	- - - -	6.8 - 8.8 -	640 - 0.29 -	63800 - 28.9 -	0.42	2
Levy et al 2015 [18]	$W = \frac{G}{2} (\lambda_1^2 + \lambda_2^2 + \lambda_3^2 - 3) + \frac{1}{2} K (lnJ)^2$	NH LE NH LE LE	Skin Calcaneus Fat Achilles Support	- 7x10 <sup>6</sup> - 205 45, 63 and 80	0.495 0.3 0.495 0.49 0.3	- - - - -	- - - - -	31.9 - 0.286 - -	3179.37 - 28.5 - -	0.43	-
Luboz et al 2015 [19]	N/A	NH - NH NH NH NH	Skin Calcaneus Fat Achilles Muscle Support	200 - 30 1x10 <sup>6</sup> 60 10 – 500	0.495 - 0.49 0.495 0.495 0.495	- - - - - -	- - - - - -	- - - - - -	- - - - - -	-	1
Levy et al 2016* [20]	$W = \frac{G}{2} (\lambda_1^2 + \lambda_2^2 + \lambda_3^2 - 3) + \frac{1}{2} K (lnJ)^2$	NH LE NH LE LE	Skin Calcaneus Fat Achilles Support	- 7x10 <sup>6</sup> - 123 45	0.495 0.3 0.495 0.49 0.3	- - - - -	- - - - -	44.66 - 0.4 - -	- - - - -	0.43	-
Lee et al 2017 [21]	$W = A_1(J_1 - 3) + A_2(J_2 - 3) + A_3(J_3^{-2} - 1) + A_4(J_3 - 1)^2$  $A_1 = 1.65\text{kPa}, A_2 = 3.35\text{kPa}$	LE MR LE LE	Skin Muscle Support U Support L	150 15 430 300	0.46 0.49 0 0	1100 1060 57.8 47.4	- - - -	- - - -	- - - -	0.4	2
Friedman et al 2019 [22]	$W = \frac{G}{2} (\lambda_1^2 + \lambda_2^2 + \lambda_3^2 - 3) + \frac{1}{2} K (lnJ)^2$	NH LE NH LE LE	Skin Calcaneus Fat Achilles Support	970.853 7x10 <sup>6</sup> 0.855 194.5 40 -100	0.495 0.3 0.495 0.495 -	- - - - -	- - - - -	324.7 - 0.286 - -	32357 - 28.5 - -	0.42	-
Zwam et al 2020 [23]	$W = \frac{2\mu}{\alpha^2} (\bar{\lambda}_1^\alpha + \bar{\lambda}_2^\alpha + \bar{\lambda}_3^\alpha) + \frac{1}{D} (J - 1)^2$	OG LE OG LE LE LE	Skin Calcaneus Fat pad Achilles Muscle Support	- 7.30 x10 <sup>6</sup> - 816x10 <sup>5</sup> 60 50	0.49 0.3 0.49 0.49 0.49 0.3	- - - - - -	2.3,0.81 - 6.82,2.51 - - -	50 - 16 - - -	2.3 - 6.82 - - -	0.4	2
Soh et al. 2020 [24]	N/A	NH NH NH NH NH NH	Skin Calcaneus Fats Achilles Muscle (PC) Support	- 20 x10 <sup>6</sup> 2000 52x10 <sup>6</sup> - 25 – 2.1x10 <sup>8</sup>	- 0.42 0.45 0.49 - 0	- - - - - -	- - - - - -	39 - 0.286 - 7.1 -	3179 - 28.5 - 80.19 -	1.5*	2 - 3 5 1.5 -

The first thing that becomes clear is the wide disparity between each of the studies in their choice of constitutive model and material properties to simulate the same tissue. Tracing the source cited for each of the assigned parameters also highlighted that all reviewed articles used material properties from existing literature (Appendix A) and none used properties measured in the heel. Whilst the majority of articles focused on the healthy foot, it is important to emphasise here that appropriate material parameters should be assigned for specific population groups (e.g. diabetic vs healthy foot). This is of particular relevance for heel ulcers as the peak plantar pressure increases by up to 7% for those with diabetes [43]. Continued development of experimental research is vital to provide more comprehensive and representative data in the future, however, the complexity and difficulties in obtaining personalised in vivo data is likely to remain.

### 3.3. Boundary conditions and loading

Boundary conditions of the foot and support surface can either be fixed or free to allow translation and rotation in a specific plane [21,22,24,28,29]. The foot can also be positioned in neutral (i.e. the position the subject naturally adopts when lying supine in bedrest) or rotated in abduction/adduction or plantarflexion/dorsiflexion to investigate the effect of different foot orientations. The way that the foot is positioned, and the types of constraints imposed on the model will significantly affect the outcomes reported in each study [22,28].

Mechanical loading of the skin gives rise to forces acting either perpendicular to the skin, described in clinical terms as pressure, or parallel to the skin, described clinically as shear. A combination of these forces is thought to be very damaging, particularly with significantly high shear, which can result in occlusion quickly [44]. To simulate a person in bedrest, the interaction between the heel and the support surface (e.g. the mattress or dressing) must be defined. One method for simulating the force of the foot is to use an unloaded and loaded MRI dataset, whereby the difference in total soft tissue thickness can be calculated and used as the target downward displacement [23,25]. It is then possible to prescribe the displacements to a set of nodes (e.g. at the heel surface) before integrating the stress over the surface on which the nodal displacements are applied, to obtain the force.

Alternatively, if the weight of the foot or lower leg is not known, then anthropometric data for an individual body segment can be used to estimate the weight as a percentage of the subject's total body weight (BW). A distributed or concentrated load (either in the form of pressure or a gravitational body force) can then be applied to the mass of the foot [21,22,27,29], foot and calf [17,28] or whole leg [26]. The majority of FE models distribute the load solely at the heel, but in reality, the load would also be distributed along the calf, upper leg and buttock. Depending on how this load is distributed, will increase or decrease the stresses, strains and contact pressure at the heel [26,28]. Furthermore, to mimic the contact behaviour between the skin-support surface or bone-soft tissue interface, researchers have either developed a frictionless model [21,24] or used a friction coefficient ranging from 0.4 to 0.43 [22,23,25], [26], [27], [28]] or 1.5 [29]. As friction is assumed to play a major role in the development of heel ulcers, the authors do not believe it is correct to negate friction in an FE model and more precise values are needed.

FE analysis has also been utilised to explore different foot orientations on heel interface pressure and strain. Experimentally, Tong et al. found that elderly participants aged  $\geq 70$  years old rested their heel at  $60^\circ$ – $69^\circ$  or  $90^\circ$ – $99^\circ$  angle to the support surface in sleep mode. The heel interface pressure was greatest when the foot was upright, and age, weight, and BMI had no significant impacts [45]. The two reviewed articles that investigated foot posture reported conflicting results. Sopher et al. found that the resulting stresses and strains were higher when the foot was inclined at  $60^\circ$  to the supporting material rather than at  $90^\circ$  [22]. Conversely, Zwam et al. found the resulting stresses and strains in the fat pad of the heel were considerably reduced when the foot was at  $90^\circ$  compared to a  $60^\circ$  abducted foot posture [28]. The foot not

only moves in abduction/adduction but also in dorsiflexion/plantarflexion. This is important as the head of the bed can often be elevated. This can cause the patient to 'slip' down the bed, causing a shear force at the supported posterior heel (which can also rotate the foot into plantarflexion). An increase in plantarflexion between 10° and 30° has been found to increase the effective stress and shear stress in the skin tissues [25]. It is therefore evident that further research is needed to fully understand the effect of different foot postures and determine the optimum foot posture for alleviating heel interface pressure and strain.

Quantifying the exact stiffness of a standard mattress is difficult unless experimental data is collected, or a specific medical brand is modelled. Therefore, it is common for multiple simulations to be run with varying Young's moduli to account for the vast number of medical devices and support surfaces available. This is itself a simplification as mattress materials generally exhibit nonlinear stress-strain behaviour. Unsurprisingly, all reviewed studies that varied stiffness properties for the support surface reported that heel loads (i.e. stress and strain) increased with the stiffness of the support [14,23,24,26,27,29]. In addition, contact pressure and/or stress and strain levels in the fat and skin tissue were reduced with a small angle  $\leq 5^\circ$  tilt (lifted or lowered) compared to a standard horizontal position [26,27]. Lee et al. also demonstrated the large degree of asymmetry of the right and left contact pressures occurring at the calves or heels (potentially accounting for why some patients have only one heel affected by a PU, or why the heel ulcers can be of different severity on either foot) [26]. The study also reported how the weight of the heels could be partly shifted to the calves by controlling the angle of the bottom part of the mattress. This is advantageous to clinical practice as the calves are at less risk of PU formation. However, care needs to be taken in interpreting these results, as in some cases, the stiffness of the mattress, coupled with an increased angle, can lead to an increase in soft tissue strain [27].

#### 3.4. Injury criteria

FE models can generate a large amount of detailed information, and interpreting these data such that simple, clinically relevant metrics can be provided is important. The output measures of the reviewed articles included: principal compressive and tensile stresses and strains, maximum shear stresses and strains, von Mises equivalent stress and strain, Green-Lagrange strain and strain energy density (SED). Injury criteria included maximum values, averages over a region and the volume in which a certain threshold is exceeded. Data was typically reported visually in the form of colour contour maps or bar graphs. Primary output measures and injury threshold criteria are shown in Table 4.

**Table 4 – Primary output measures, injury thresholds and validation stated in each of the reviewed articles.**

Study	Primary Output Measures	Thresholds (dimensionless unless stated)	Validation
Gefen 2010 [16]	Maximal soft tissue pressure	None	None
Sopher et al 2011 [17]	Peak compressive strain Peak tensile strain Peak shear strain Peak SED Peak compressive stress Peak tensile stress Peak shear stress Peak VM stress	SED $\geq$ 0.3, 0.5 or 0.7 kPa and VM stress $\geq$ 1.5, 2.0 or 2.5 kPa	Previous experiments in animal models and tissue-engineered constructs [46,47]
Levy et al 2015 [18]	Effective Green-Lagrange strains Max shear strain Peak effective compressive stress in the AT Peak shear Cauchy stress in the AT Average CP under the heel	Effective strains between 0.2 and 0.5 and effective strains exceeding 0.5	Pressure-strain curves reported by Li et al [48]
Luboz et al 2015 [19]	Max VM strain Volume of largest cluster with VM above 50%	20% and 50% VM strain	Strains reported in the buttock sub-dermal tissue, and strain distributions in muscle [9,10,41]
Levy et al 2016* [20]	Effective Green-Lagrange strains Peak effective compressive stress in the fat and skin Peak shear stress in the fat and skin	Effective strains between 0.2 and 0.5 and effective strains exceeding 0.5	Previous study by Levy et al [18]
Lee et al 2017 [21]	CP distribution with a mattress at 0° and 5° tilt	None	Experimental data with pressure mattress for the same subjects
Friedman et al 2019 [22]	Max effective (VM) stress Max shear stress Max Lagrange strains Max SED	Effective and shear stress injury thresholds were calculated using the average maximal effective and shear stresses and vary as function of mattress stiffness. Lagrangian strain thresholds in skin and fat also proposed.	None
Zwam et al 2020 [23]	Max shear strain Nodal CP at the heel and calf	A threshold is not explicitly stated in the text, but Max shear strains are shown specifically for 0.25 – 0.40	Internal strain values for stiffer mattress [17,19] CP experimental data [49,50]
Soh et al [24]	Stress	None	None

These different stress and strain measures and different ways of defining an injury threshold will give very different results. Maximum stress and strain values tend to be very mesh dependent and can become unrealistically high at sharp corners or discontinuities in the mesh, and so averaging over a region or using a volume that exceeds a threshold may give better results [46]. Measures such as SED and von Mises stress give a convenient single scalar value but it is not clear how they could be related to any physiological injury mechanism. The von Mises stress is a yield criterion for metals, and there is no evidence that it predicts injury in soft tissues. To the authors' knowledge, the only experimental data on injury thresholds is that of Oomens et al. which showed that the maximum shear strain was the best predictor of injury, and therefore this is probably the most appropriate criterion to use [47]. Of course, there are many other factors involved in PU formation and so even the best injury criterion gives only a part of the picture.

### 3.5. Verification and validation

As computational models become more complex, a consistent and robust methodology for model validation through rigorous experimental measurements is needed [48]. Although the prospect of using simulations in clinical applications is exciting, caution must be exercised. Many studies that use FE analysis have done little to establish the validity of their methods via thorough experimentation. Instead, indirect validation (data from existing literature) is used to compare the contact pressure and stress/strain behaviour of specific tissues (Table 4). Since all the published studies share the same limitations this does not provide any meaningful validation of the results.

Two different levels of confirmation are needed before we can be confident that FE models can predict the risk of pressure injury. The first stage, which we can call verification, is to test whether the models accurately predict strains in the tissue. This could be done by comparison with medical imaging data or other experimental methods of measuring tissue strains [[48], [49], [50]]. The second stage, validation, would be to test the wider question of whether these methods can correctly predict injury risk. This is a more challenging problem and would presumably require an extensive clinical trial. Until it can be established that these new methods can increase the level of care clinicians are able to provide, their usefulness is limited. The studies we reviewed did not have effective verification or validation, and so their conclusions must be treated with caution.

## 4. Discussion

This review summarises the current challenges in developing an effective FE model of the foot for heel ulcer prevention and what existing published models can tell us about the clinical questions we posed in the Introduction. We must bear in mind that mechanical loading is only one of many factors in the aetiology of PUs and therefore analysing the stresses can only give us one part of the picture.

FE modelling is a powerful mathematical tool that enables the internal stress and strain analysis of complex structures with geometrical and material nonlinearities. The intricate anatomy and mechanics of the human foot have created difficulties in obtaining *in vivo* measurements of the heel soft tissue under load. Computer-based simulations have therefore enabled researchers to generate results quickly for several different scenarios, which would not be possible through *in vivo* experimentation. To date, there has been limited interest in FE studies of the heel in the supine position, despite the increased concern of PU formation in bedrest. The first paper to model the biomechanics of heel ulcers was written in 2010 [21], with only eight papers having continued the development of FE modelling in this field. This has therefore brought about several key limitations which will be addressed in turn below.

Cost, ethics, time, and restricted access to a scanning system have meant that published computational models of heel ulcers have predominantly used existing cadaveric datasets or used a model that has been manipulated to simulate atypical anatomy. Whilst this has provided an idea of the mechanical behaviour of soft tissues it has been subject to the following assumptions: the regions which have been segmented and how 'soft tissue' has been defined, the constitutive model and the material properties assigned, the boundary conditions and loads applied, atypical or healthy anatomy, the heel-support surface interaction, foot orientation, the type of stress and strain reported, and the injury criteria used.

All studies included in this review focused on modelling the healthy foot of a male subject(s), with none modelling female foot geometry. It is well documented that PUs affect both men and women and that men have longer and broader feet than women and it is not correct to assume that this is algebraically scalable (i.e. a female foot is a smaller version of a male) [51,52]. Secondly, with the exception of the diabetic foot modelling by Levy et al. none of the studies assessed the implication of other foot deformities (e.g. Haglund's deformity) which could potentially alter the soft tissue mechanics of the foot. The force exerted at the heel and the interface pressure were also not assessed at the time of scanning. This could be implemented using a load cell and pressure mat to assign subject-specific loads and boundary conditions. Although a limited number of studies are presented in this paper, it highlights the necessity for increased research and FE modelling of different patient groups to identify those at risk and those requiring individualised treatment/prevention methods.

Care must also be taken when substituting subject-specific data into a general dataset or 'filling' damaged regions with healthy soft tissue. Luboz et al. assumed that the soft tissue surrounding the calcaneus remained the same for each subject, such that all 18 calcanei were positioned so that their most posterior (lower) tips would be superimposed [19]. Whilst this enabled a direct comparison of the strains to be made across all 18 models, it is in fact anatomically inaccurate. The soft tissue surrounding the calcaneus is thin (approximately 3.8 mm between the bone and surface of the skin). This thickness will not only vary between patients but will also vary with different foot orientations. The attachment of the Achilles tendon will be dependent upon the shape and size of the calcaneus, particularly in atypical foot geometry such as those with Haglund's deformity. This will change the mass of adipose tissue known as Kager's fat pad, which in turn will affect the mechanics of the foot [46]. Similarly, damaged soft tissue as evident in a patient with DTI is best modelled as an ulcerated foot and not as a healthy foot model, as the reconstructed soft tissue anatomy may be inaccurate.

Material models are often simplistic and do not properly represent the nonlinear, anisotropic behaviour of the different tissues. A vast array of parameter values are therefore used, often from outdated literature or tissue dissimilar to the foot tissues modelled. Ideally, measurements would be taken on a living subject during the imaging process to allow subject-specific material parameters to be assigned to their individual geometry, although this would be very difficult. Failing that, accurate data from multiple measurements on representative tissue from the correct anatomical site is needed, particularly for tissues such as the heel fat pad which has never been tested on the posterior part of the heel and is likely to have different properties from the weight bearing tissue on the sole of the foot.

FE analysis is only useful if the meshed geometry and material parameters have been appropriately assigned and the correct output measures are reported. The assignment of material properties that accurately represent the complexity and behaviour of these tissues is critical and therefore requires continued experimental research to further develop these models and identify damage criteria. Oomens and colleagues have made a significant contribution to the understanding of soft tissue mechanics through in vivo animal studies, identifying that shear strains above a certain threshold could cause direct deformation damage of skeletal muscle [53]; this may provide greater insight into the risk of DTI compared to pressure mapping measures at the skin interface [15]. Yet the majority of studies do not

validate their model by experimental data due to the difficulties in obtaining in vivo human or animal data.

Another important factor that is ignored in these studies is the effect of time and duration of loading. This is important in two respects, firstly the tissues are assumed to behave elastically with no change in deformation with time of loading, and secondly the likelihood of injury depends not just on the magnitude but also on the duration of loading. The first point is difficult to address with the current state of the art of soft tissue modelling. It may well be that deformation does change with time but we do not currently have sufficient data or appropriately detailed material models to be able to address this. On the second point, again we lack detailed information on the time evolution of injury criteria, but we can say with some confidence that a higher strain in the tissue is likely to lead to a greater risk of an injury occurring after a shorter period of loading. Comparative studies that demonstrate lower strains in a quasistatic model can therefore reasonably be interpreted as showing a reduced risk and/or a longer time before injury occurs. Although the studies we reviewed have a number of significant limitations, they do offer some insights into the clinical questions we posed in the Introduction. We will consider each of these in turn:

#### *How are the internal soft tissue strains influenced by foot posture?*

Interface stresses between the heel and its support surface are a consequence of external force (gravity), the biomechanical properties of the soft tissue and geometry of the heel, the stiffness of the support surface, the friction at the interface and the orientation of the foot. Numerical modelling has previously demonstrated that individuals with comparable interface pressures can have significantly different internal stresses and strains [15]. Different foot postures have shown how sensitive the internal strains are to abduction, adduction and plantarflexion [22,25,28]. The next step would be to model the ankle joint to further investigate the effect of plantarflexion and dorsiflexion on the foot, particularly with different combinations of abduction and adduction. The inclusion of the knee joint and upper leg/buttock would also help to simulate the load distribution of the total leg and ensure the correct load on the heel.

#### *How are the internal soft tissue strains influenced by the slope and stiffness of the mattress?*

Only two of the reviewed studies assessed the slope and stiffness of the mattress but only one reported the influence of the slope with regards to soft tissue strains. Friedman et al. varied the support angle according to common surgical bed positions (Trendelenburg position, horizontal position and reverse Trendelenburg position) and found that a small angle  $\leq 5^\circ$  tilt (lifted or lowered) reduced the stress and strain levels in the fat and skin tissue when compared to a standard horizontal position [27]. However, in some cases, the stiffness of the mattress, coupled with an increased angle, lead to an increase in soft tissue strain [24]. Although Lee et al. did not report data on the internal strains, the paper did report that the contact pressure in the heel and calves were reduced when the angle of the lower part of the mattress increased. This argues the need for further research to be carried out in order to fully understand the influence of the support angle in each of the above positions and how this is affected when the stiffness of the mattress is varied. Repositioning is one of the main strategies used in clinical practice for the prevention of PUs. Knowing whether there is an optimum bed position, coupled with an optimum mattress stiffness is an important area to establish clear results.

Many of the published studies represented the mattress as a simple linear elastic material which will not give accurate results where there are significant deformations occurring at the heel. The other studies used a neo-Hookean model which correctly accounts for large deformations but still behaves in a linear elastic way, whereas the behaviour of real mattress materials is nonlinear. It is important to note that the stiffness of the mattress will depend not only on the material stiffness but also on its thickness. With these limitations in mind, it is difficult to relate the results of the studies to the actual selection of mattresses or support surfaces in clinical practice. All the studies concluded, as would be expected, that a mattress



material that is too stiff will increase the strains in the soft tissue and therefore the risk of injury, but none identified an optimum stiffness or characteristics that could minimise the risk.

*How are the internal soft tissue strains influenced by the friction coefficient at the skin – surface interface?*

The various studies used a wide range of friction coefficients, from 0 to 1, which more than covers the range likely to be encountered in practice, but most chose values around 0.4. Friction is mainly important where there is a shearing force on the heel, for example because the upper part of the bed has been raised and the patient has a tendency to slide down. Zwam et al. found that friction coefficients below 0.4 had a strong influence on tissue stresses and that from 0.4 upwards sliding did not occur and so the precise value was unimportant [28]. Since 0.4 is about the level of friction that seems to be encountered in practice [54,55] this suggests that significantly reducing friction or taking other steps to reduce shear loads could reduce internal tissue strains and hence the risk of injury. However, this conclusion comes only from a single study and has not been confirmed by others or in different situations.

Overall, these studies do not provide really convincing evidence to answer these clinical questions. All had technical limitations, and none modelled mattress materials realistically enough to be really confident that the predicted strains are correct. We conclude therefore that further work is needed with more attention to accurately modelling the material behaviour and other aspects. We must remember also that mechanical loading is only one factor that may cause injury and other factors such as microclimate are also critical.

MRI imaging now offers the possibility of in vivo strain measurements using image registration techniques and this is one way in which computational models of the heel could be validated. Another might be to construct phantoms with appropriate tissue properties.

It is widely acknowledged that there can be significant numerical and computational error in using FE methods, as well as a frustrating lack of speed or reliability. However, if these factors are known and appreciated, it is possible to use these methods to start to gain real insights into the behaviour of soft tissues and to produce useful practical predictions. The FE models to date have provided an insight into the complexity of modelling the soft tissues of the foot. Understanding PU aetiology and improving risk assessment through early detection of injury depends on the implementation of reliable imaging modalities and thorough and extensive validation of each individual step of the FE modelling process.

FE modelling alone will only provide partial information and as such future studies should strongly consider the implementation of experimental data from the same subject. Validation is critical for any clinically relevant application of FE modelling but at the same time it remains one of the most challenging aspects of computational biomechanics.

The evaluation of FE models against experimental data in other computational biomechanical analysis for PU prevention has typically involved animal studies and/or imaging (e.g MRI, low dose biplanar X-ray). A number of approaches have been used to measure soft tissue response in the buttock or sacrum, for example: assessing the volume of the tissue with strains in a certain strain interval to compare loading regimens [[56], [57], [58], [59]]; a comparison of peak strains and stresses in spinal cord injury patients with sitting-acquired DTI [60]; examining three different strain parameters (max in-plane compressive strain, max in-plane shear strain and SED) with respect to measured compression-induced damage [61]; and a comparison of the simulated contact pressure and analysis of the maximum Green Lagrange shear strains in the muscles [8]. Methods of this kind, followed by validation of the whole approach through clinical trials, are needed before we can confidently draw clinical conclusions from these studies. Their clinical value will remain limited until thorough validation has been completed.

## **5. Conclusion**

Only a few studies have attempted to model the mechanics of heel ulcers and all have significant limitations. Further work is needed to develop models that are sufficiently robust and well validated to draw reliable clinical conclusions. Although the studies that have been published to date demonstrate the possibilities of the technique and suggest some interesting preliminary conclusions, all have limitations in their choice of subjects, imaging and mesh generation, material models and parameters, and their boundary conditions. None have been properly validated against independent experimental measurements and many have very significant limitations such as the use of generic “soft tissue” properties, instead of correctly modelling the different tissues. All of these difficulties can be overcome with further research and development. Our recommendations for future studies are therefore summarised in Table 5.

**Table 5 – Recommendations and considerations for future studies (where essential and desirable (*italics*) criteria is stated).**

Stage of FE development	Essential and Desirable criteria for each stage of the FE process
Aim	<ul style="list-style-type: none"> <li>▪ Clearly define a goal of the FE model.</li> <li>▪ State the scientific research question(s) that the development of the FE model will answer.</li> </ul>
Imaging	<ul style="list-style-type: none"> <li>▪ As a minimum, ensure the imaging sequence captures appropriate detail for the following anatomical structures: Calcaneus, Achilles tendon, heel fat pad, soft tissue.</li> <li>▪ Where the skin envelope is not visible, assume the skin layer is 1-2mm as per existing literature.</li> <li>▪ Include the right or left foot of a male subject for comparison with previous studies.</li> <li>▪ <i>Where possible include data for a female foot.</i></li> <li>▪ <i>Image both a range of healthy feet and atypical geometry (e.g. Haglund’s deformity).</i></li> <li>▪ <i>Where possible include additional parts of the leg (e.g. the calf, upper leg, buttock).</i></li> </ul>
Dataset	<ul style="list-style-type: none"> <li>▪ Choose an appropriate dataset that best represents those affected by pressure ulcers (taking into account age, weight, height, gender etc). Ensuring that any material parameter values are then selected for the same population group.</li> <li>▪ Do not ‘fill’ regions of damaged tissue with healthy tissue.</li> <li>▪ Avoid manufacturing artificial datasets to represent anatomical differences or pathologies. Scan representative individuals wherever possible.</li> </ul>
Software	<ul style="list-style-type: none"> <li>▪ Clearly state which segmentation software and FE solver was used, inc version (e.g. ScanIP 2018 and FEBio v2.1).</li> <li>▪ <i>State the PC properties and simulation run times (e.g. Core i7, Windows 10, 64 GB RAM, 8h/model).</i></li> </ul>
Modelling	<ul style="list-style-type: none"> <li>▪ As a minimum, all models should include the calcaneus, Achilles tendon, heel fat pad and soft tissue.</li> <li>▪ Use an appropriate mesh between the heel and contact surface.</li> <li>▪ Ensure a thorough understanding of non-linear constitutive models, boundary conditions and loading capabilities of the FEA software used, and the differences in defining equations (e.g. between FEBio and Abaqus software).</li> <li>▪ Report the type of mesh and number of elements in model.</li> <li>▪ <i>Additional subcutaneous layers, muscles and soft tissue should be included where appropriate.</i></li> <li>▪ <i>Inclusion of a mattress, medical device/dressing should be included where appropriate.</i></li> </ul>

Material Parameters	<ul style="list-style-type: none"> <li>▪ Use appropriate material models and parameters for the individual tissues, rather than a generic “soft tissue” model.</li> <li>▪ Where existing literature is cited, ensure that the source has characterised the tissue layer relative to the FE model.</li> <li>▪ Use appropriate material models and obtain accurate parameters for mattress stiffness.</li> <li>▪ <i>Seek to obtain accurate data from the correct anatomical location in representative individuals.</i></li> <li>▪ <i>Seek to obtain subject-specific experimental data from the same individual that has been imaged.</i></li> <li>▪ <i>Tabulate material properties for ease of reading.</i></li> </ul>
Boundary Conditions	<ul style="list-style-type: none"> <li>▪ Use an appropriate friction coefficient that has been measured for the combination of materials.</li> <li>▪ Use the actual images to calculate the weight of the foot and leg (or use body loads in the FE model) and consider the load sharing between the heel, calf and thigh.</li> <li>▪ Do not use generic anthropometric data to calculate the weight of the foot (if using a cadaveric or CAD dataset).</li> <li>▪ <i>For MRI studies, consider the development of an MRI compatible device to allow the load to be obtained during scanning.</i></li> </ul>
Sensitivity Analysis	<ul style="list-style-type: none"> <li>▪ Run a mesh sensitivity analysis by changing the element size at the region of interest.</li> <li>▪ Report foot posture in the subject’s adopted position in bedrest, 60° and 90° incline to the support surface (abduction) and 120° and 135° (adduction) [23].</li> <li>▪ <i>Where the mattress is included, vary the stiffness to show the effect of a soft and stiff support surface.</i></li> <li>▪ <i>Where the mattress can be lowered or raised, vary the angle at 5°.</i></li> <li>▪ <i>Where the ankle joint is present, report plantarflexion at 10°, 20° and 30° and dorsiflexion where possible.</i></li> </ul>
Output Measures	<ul style="list-style-type: none"> <li>▪ The different stress and strain outputs reported are confusing and cause ambiguity when defining an injury threshold. Maximum shear strain should be reported as a minimum as this is currently the most appropriate criterion to use [55][45].</li> <li>▪ Include tabulated or graphical results of each simulation to aid objective comparison.</li> </ul>
Validation	<ul style="list-style-type: none"> <li>▪ Validate models against experimental measurements or other independent data, not just by comparison to previous studies.</li> <li>▪ <i>If possible, measure tissue deformation by imaging to validate models.</i></li> </ul>
Open access	<ul style="list-style-type: none"> <li>▪ <i>Where possible, consider making models openly available to advance future heel ulcer research.</i></li> </ul>

The authors would like to emphasise here that it is imperative to develop a model that answers a specific research question. This will determine how sophisticated the FE model needs to be in order to answer the question(s) posed. It is easy to fall into the trap of developing a model just “to make a patient-specific model” or an overly complex model that has a vague concept without clear research aims. Therefore, the focus of any FE research should always start with a clearly defined goal and a scientific question to answer. This will define how far the researcher has to go with fine tuning and validating their model and how many of the recommendations proposed in Table 5 they have to achieve.

The development of appropriate measurement methods to obtain reliable model input data remains a key challenge. The personalisation of parameters and the potential complexity of the FE model will therefore lie in the research question posed. There is evidence in all the reviewed studies that each parameter is of importance, however the evidence to date is not enough to be able to prioritise the importance of the parameters.

We look forward to the development of more rigorous models in the future and we anticipate valuable clinical conclusions, thorough preclinical testing of new products and perhaps the development of more personalised treatments tailored to the anatomy and mechanics of individual patients.

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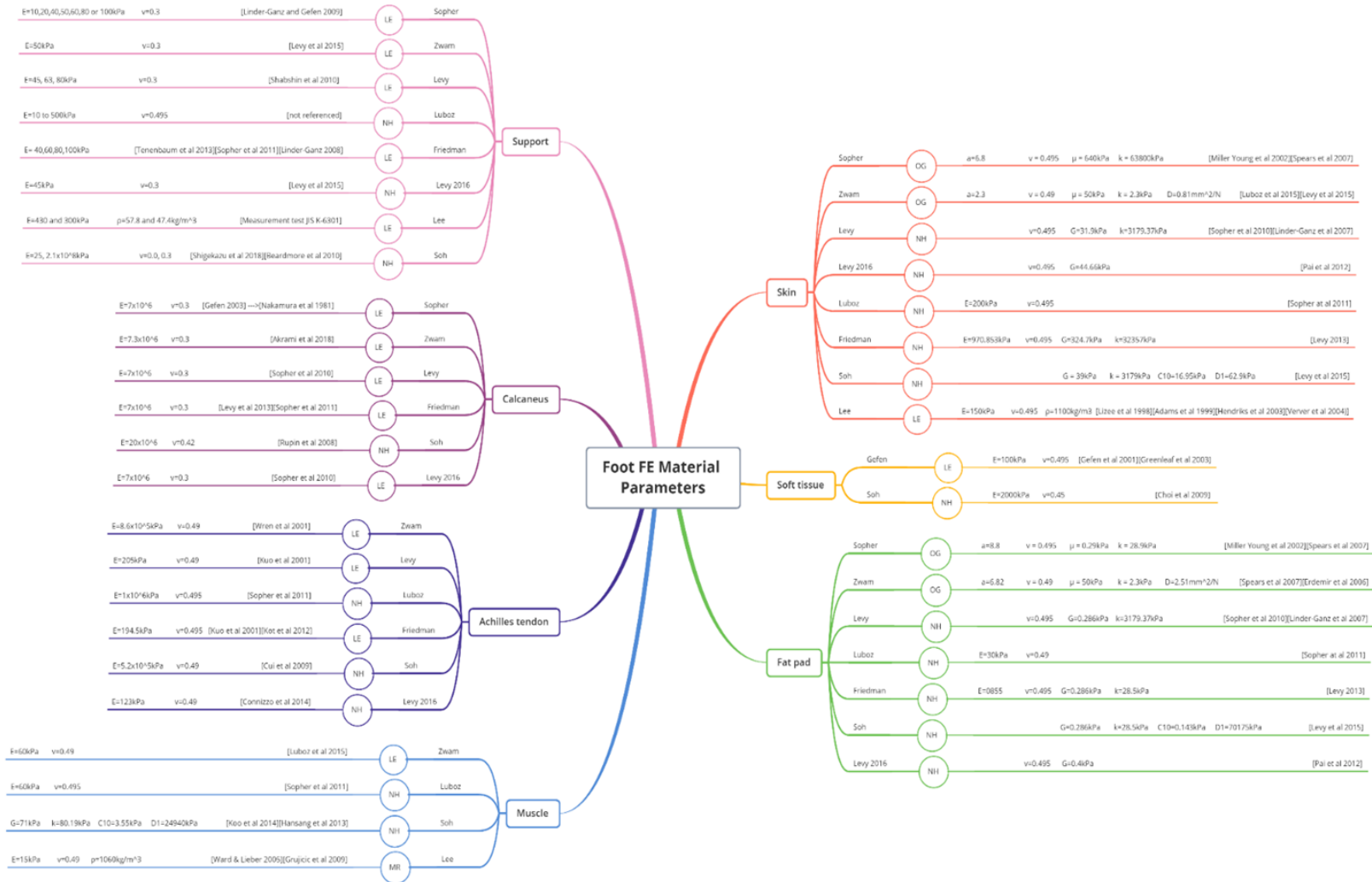
## **Declaration of competing interest**

The authors certify that no conflict of interest is raised by this work.

## **Appendix A. Supplementary data**

The following is the Supplementary data to this article:

# Appendix A– Constitutive model and material properties for each of the reviewed studies with original source shown in square brackets



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