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Technical note

Shore hardness is a more representative measurement of bulk tissue biomechanics than of skin biomechanics.

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ABSTRACT

To support the effective use of Shore hardness (SH) in research and clinical practice this study investigates whether SH should be interpreted as a measurement of skin or of bulk tissue biomechanics. A 3D finite element model of the heel and a validated model of a Shore-00 durometer were used to simulate testing for different combinations of stiffness and thickness in the skin and subcutaneous tissue. The results of this numerical analysis showed that SH is significantly more sensitive to changes in skin thickness, relatively to subcutaneous tissue, but equally sensitive to changes in the stiffness of either tissue. Indicatively, 25% reduction in skin thickness (0.3 mm thickness change) or in subcutaneous tissue thickness (5.9 mm thickness change), reduced SH by 7% or increased SH by 2% respectively. At the same time, 25% reduction in skin stiffness (10.1 MPa change in initial shear modulus) or of subcutaneous tissue (4.1 MPa change in initial shear modulus) led to 11% or 8% reduction in SH respectively. In the literature, SH is commonly used to study skin biomechanics. However, this analysis indicates that SH quantifies the deformability of bulk tissue, not of skin. Measurements of skin thickness are also necessary for the correct interpretation of SH.

1. Introduction

Shore hardness (SH) is a measurement of a material's resistance to indentation which was initially developed and is most commonly used for the characterisation of polymers, elastomers and rubbers [1]. At the same time, its ease of use, non-invasive and cost-effective nature highlight SH as an excellent candidate method for the *in vivo* measurement of soft tissue biomechanics in clinical research and within clinical practice [2,3,12,4–11].

To measure - SH *in vivo*, a specialised durometer (Fig. 1a) is pressed against the skin surface by the full weight of the device before taking a hardness reading (Fig. 1b). The instrument has an internal spring mechanism that pushes a small metallic tip to indent the skin surface. The final SH measurement is determined by the depth of indentation and is given a dimensionless value between 0 and 100 with a high value of SH indicating a high resistance to indentation.

In literature, SH has been used to monitor the effect of skin pathologies on skin hardness [2–4] and to study the *in vivo* biomechanics of the soft tissues of the sole of the foot (plantar soft tissue) [5–11,33]. The latter application is particularly relevant in the case of diabetic foot complications where, according to literature, being able to quantify the mechanical characteristics of plantar soft tissues could enhance the prediction and clinical management of diabetic foot ulceration [12]. However, exploring the potential clinical value of SH also requires a deeper understanding of the physical meaning of this mechanical measurement and of the parameters that affect it.

In conventional engineering materials, such as metals, resistance to indentation and hardness is linked to the material's tribological performance. However, in the case of soft tissue mechanics, the physical meaning of hardness is not as clear. Even though, resistance to indentation is related to the tissue's stiffness, it is not clear which aspects of the complex non-linear mechanical behaviour of soft tissues are assessed by SH.

Another area of uncertainty is the effect of the layered structure of superficial soft tissues. Whilst SH has been predominantly used as a measurement of skin's resistance to indentation [2–6,9–11] there is also a small number of studies where SH is reported as a measurement of bulk tissue biomechanics [7,8,33] (i.e. skin and subcutaneous tissue combined). Identifying the correct interpretation of SH depends on the effect of subcutaneous tissues on the measurement and whether this can be

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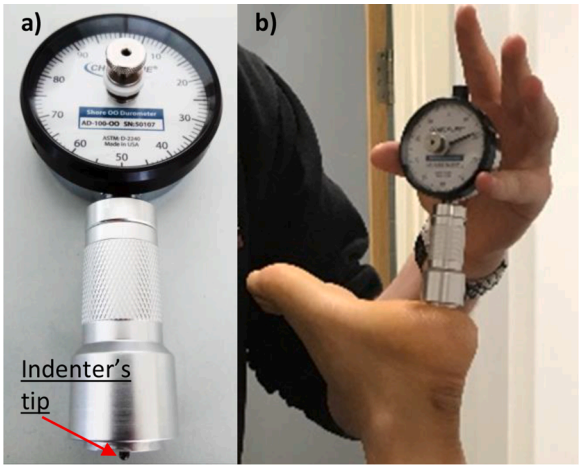

Fig. 1. A Shore-00 durometer (a) and the testing set-up for the measurement of SH at the heel (b).

considered negligible. Previous research has demonstrated that indentation tests that use small indenters (such as SH) are affected significantly more by the thickness of skin compared to the thickness of the subcutaneous tissue [13]. Based on this finding it is reasonable to suspect that SH is more relevant to skin rather than subcutaneous or bulk tissue biomechanics [13]. However, tissue thickness is only one aspect of the problem. If SH is indeed a representative measurement of skin biomechanics, then it should also be significantly more sensitive to changes in skin stiffness relative to changes in the stiffness of subcutaneous tissues. To the authors' knowledge, this hypothesis has not been directly tested, which might hinder the correct use and interpretation of *in vivo* measurements of SH.

In this context, the present study uses finite element (FE) modelling to test whether a change in SH should be interpreted as a change in skin biomechanics or as a change in bulk tissue biomechanics. In addition, the relationship between the non-linear hyperelastic behaviour of soft tissues and SH will also be explored.

2. Methods

A 3D model of a Shore-00 durometer was created and validated before being used to simulate SH testing at the heel in a series of static FE analyses. FE modelling was focused on the plantar soft tissue becasue of

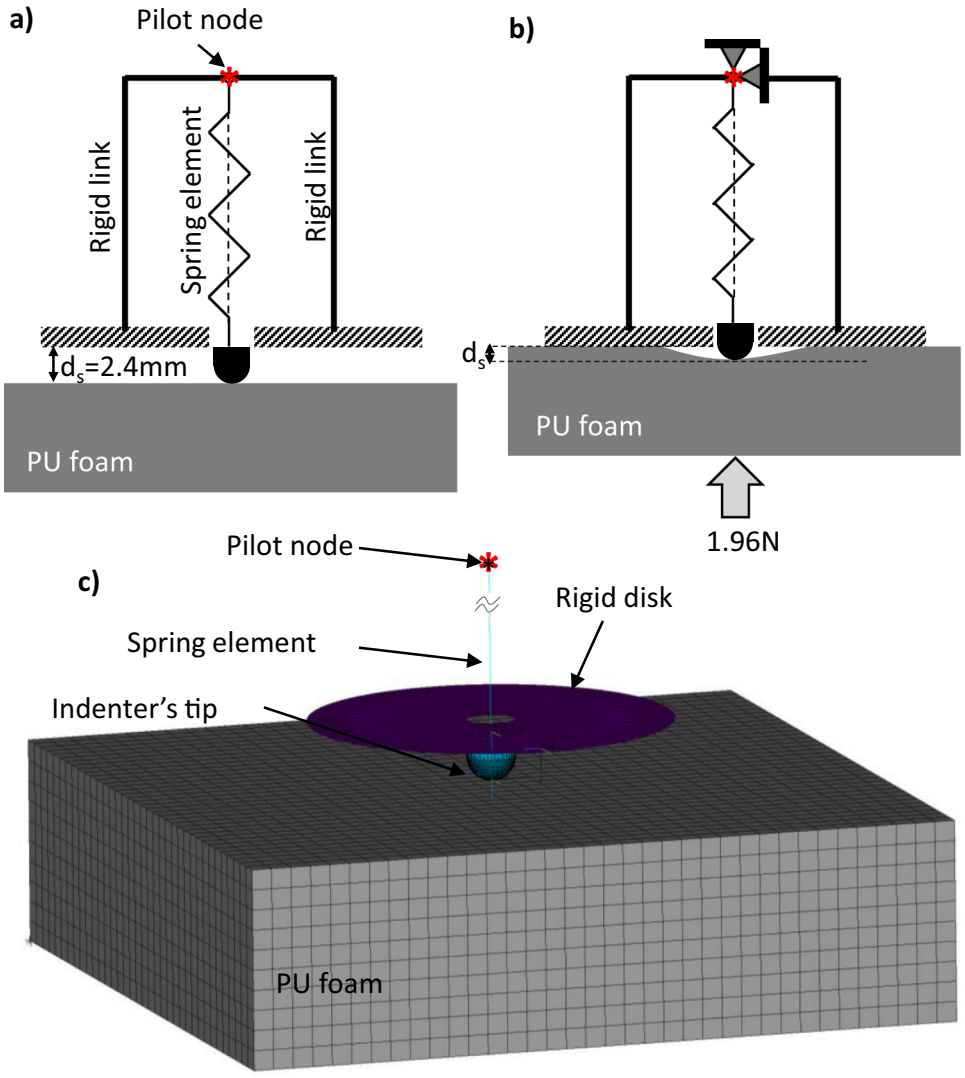

Fig. 2. A simplified view of the Shore-00 durometer model showing the durometer in contact with the surface of the tested material before indentation (a). The boundary conditions and applied load during simulated testing (b). The FE model used for validation (c).

the importance of tissue biomechanics for the study and clinical management of diabetic foot complications [6,12,16]. All numerical analyses were performed using ANSYS 2021.R1(ANSYS, Canonsburg, PA, USA).

2.1. FE model of the Shore-00 durometer

The model of the Shore-00 durometer comprises three main parts: a rigid cylindrical indenter with a semi-spherical tip (diameter: 2.4 mm), a rigid disk (diameter: 18 mm) simulating the bottom surface of the durometer and a pre-tensed spring element that simulates the internal mechanism of the durometer. The model of the durometer is controlled with the help of a pilot node which is rigidly connected to the rigid disk and linked to the indenter's tip through the spring element (Fig. 2a). During the measurement of shore hardness, the rigid disk is pressed against the surface of the tested material with a net force equal to the durometer's weight (1.96 N). At the same time the force at the indenter's tip, which is defined by the durometer's internal mechanism, increases linearly with the tip's displacement relative to the rigid disk (Fig. 2b). The initial distance between the indenter's tip and the surface of the rigid disk (d_s) is 2.4 mm, and the magnitude of the force on the tip increases linearly from the pretension value of 0.23 N (for $d_s = 2.4$ mm) to a maximum value of 1.1 N when the tip is fully pushed inside the durometer (for $d_s = 0$). Because hardness is determined by indentation depth, the value of hardness also increases linearly with the relative displacement of the tip from zero (for $d_s = 2.4$ mm) to a maximum value of a hundred (for $d_s = 0$).

For the simulation of the hardness test, the durometer pilot node was completely fixed, and a force of 1.96 N was imposed on the tested material along the durometer axis. Hardness was calculated from the final distance between the indenter's tip and the rigid disk.

The accuracy of the durometer model was tested for a polyurethane foam with known mechanical properties ($\mu_{foam} = 39.6$ kPa, $\alpha_{foam} = 19.3$, $\nu_{foam} = 0.06$, Eq. (1)) [15] which is used in therapeutic footwear. To this end, Shore-00 hardness was measured on twelve sites on a 10 mm thick material sheet (width = length = 150 mm). The FE model of the Shore-00 durometer was then used to simulate the hardness test (Fig. 2c) enabling the direct comparison between experimentally measured and numerically estimated Shore-00 hardness.

The interface conditions between the tested material and the durometer's tip or rigid disk were simulated as frictionless contact [14]. This was based on a sensitivy analysis indicating that the value of the friction coefficient between the durometer and the polyurethane foam had very little effect on the estimated Shore hardness.

The foam's mechanical behaviour was simulated using the Ogden hyperelastic foam material model (1st order):

$$W = \frac{\mu_{foam}}{\alpha_{foam}}\left(J^{\alpha_{foam}/3}\left(\bar{\lambda}_1^{\alpha_{foam}} + \bar{\lambda}_2^{\alpha_{foam}} + \bar{\lambda}_3^{\alpha_{foam}}\right) - 3\right) + \frac{\mu_{foam}}{\alpha_{foam}\beta_{foam}}\left(J^{-\alpha_{foam}\beta_{foam}} - 1\right) \quad (1)$$

where $\bar{\lambda}_p^{\alpha_{foam}} (p = 1, 2, 3)$ are the deviatoric principal stretches, J is the determinant of the elastic deformation gradient and μ_{foam}, α_{foam} and β_{foam} are the material coefficients. Coefficients μ_{foam} and α_{foam} are related to the material's initial shear modulus and strain hardening/softening while β_{foam} is directly related to the material's Poisson's ratio (ν).

The experimentally measured and the numerically estimated Shore-00 hardness values were 66±2 and 63, respectively (4% difference). The very good agreement between the experiment and FE simulation indicates that the model of the Shore-00 hardness test is accurate, provided that the material properties of the tested material are accurately known.

2.2. FE model of hardness testing at the heel

An anatomically accurate 3D model of the heel [16] was modified to include a layer of skin (thickness = 1.32 mm) [11] and to simulate the hardness test (Fig. 3). The volumes of subcutaneous tissue and skin were fully bonded to one another. This model was designed based on coronal MRI images (1.5 T MRI scanner, T1 weighted 3D Fast Field Echo) of the left foot of a healthy individual [16]. The in-plane and out-of-plane resolution of the images was 0.23 mm and 1.00 mm, respectively. The 3D geometry of the heel was reconstructed using ScanIP (Simpleware, UK) before being imported into ANSYS for analysis. In the final model, the thickness of the subcutaneous tissue along the axis of the SH durometer was equal to 23.65 mm.

Due to the nature of the applied loading only a cylindrical section of the heel model was meshed (Fig. 3). This cylindrical section was directly over the apex of the calcaneus, and its diameter was significantly bigger than the diameter of the durometer (67% wider than the base of the durometer). A preliminary analysis indicated that the results of the simulation were not affected by this simplification. More specifically, the results from the cylindrical section model were compared against a model that included the entire heel. Including the entire heel into the analysis substantially increased the computational time of the analysis but changed the estimated SH only by 0.2% (Supplementary material).

The volumes of skin and subcutaneous tissue were meshed using four-node tetrahedral elements with enhanced strain formulation (Solid185). Element size was decided through a convergence analysis to eliminate any mesh dependency phenomena. The final FE model comprised 183,888 elements in total. Because of the relatively small thickness of the skin model, the number of elements along its thickness could have a significant effect on the model's behaviour. It was found that at least two elements were needed along skin thickness to minimise mesh dependency phenomena (Fig. 3). Enhanced strain formulation was used as a countermeasure against the artificial stiffening (due to volumetric locking) of four-node tetrahedral elements when these are used in incompressible or nearly incompressible materials [17].

Given that bone is considerably stiffer than the soft tissues of the foot and that the forces applied to the model are relatively low, the calcaneus was assumed to be rigid. The rigid calcaneus was modelled by rigidly linking all subcutaneous tissue nodes on the interface with the calcaneus to a pilot node (Fig. 3). For the simulation of the hardness test, a force of 1.96 N was imposed to the calcaneus pilot node along the durometer axis. The remaining two translational and three rotational degrees of freedom of the calcaneus pilot node were fixed. The durometer pilot node was completely fixed (Fig. 3).

The mechanical behaviour of the subcutaneous tissue and skin was simulated using the 1st order Ogden hyperelastic material model [16, 18–20]:

$$W = \frac{\mu}{\alpha}\left(\bar{\lambda}_1^{\alpha} + \bar{\lambda}_2^{\alpha} + \bar{\lambda}_3^{\alpha} - 3\right) + \frac{1}{d_k}(J-1)^2, \quad (2)$$

$$G_0 = \frac{1}{2}(\mu\alpha), \quad (3)$$

Where $\bar{\lambda}_1^{\alpha}$, $\bar{\lambda}_2^{\alpha}$, $\bar{\lambda}_3^{\alpha}$ are the deviatoric principal stretches, J is the determinant of deformation gradient and μ (Pa), α (unitless), and d_k (Pa^{-1}) are material coefficients. Coefficient α is indirectly related to the tissue's strain hardening/softening behaviour while both μ and α are used to calculate the material's initial shear modulus (G_0)(Eq. (3)). The initial shear modulus is related to the initial slope of the material's stress-strain curve (i.e. in an undeformed configuration) and therefore it can be used as an indirect assessment of initial tissue stiffness. Parameter d_k is a function of both the effective Poisson's ratio (ν) and the initial shear modulus (G_0):

$$d_k = \frac{3(1-2\nu)}{G_0(\nu+1)} \quad (4)$$

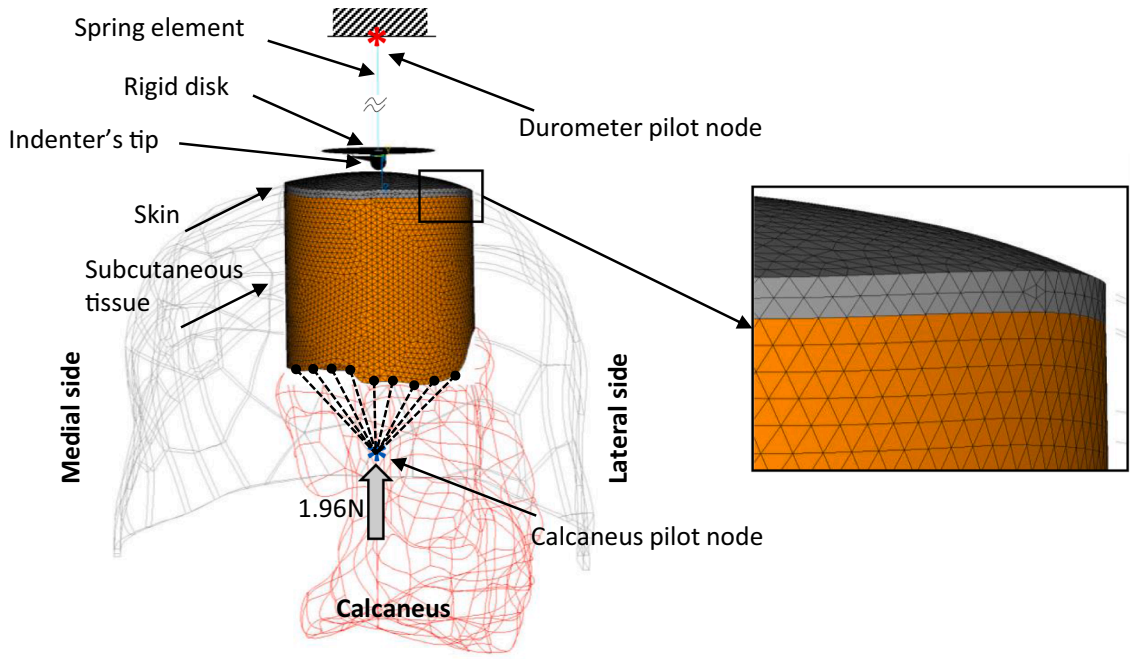

Fig. 3. Frontal view of the meshed model of the SH test at the heel combined with an outline of the entire heel geometry (for reference). The pilot nodes used to support the durometer (durometer pilot node) and load the model (calcaneus pilot node) are also shown.

Reference values of μ and α were adopted from the literature for skin (μ_{skin} = 3.57 kPa, α_{skin} = 22.71) [19] and subcutaneous tissue ($\mu_{sub.}$ = 4.82 kPa, $\alpha_{sub.}$ =6.82) [20]. Both tissues were assumed to be nearly incompressible (ν = 0.475) [18].

2.3. Parametric analysis

A parametric investigation was performed to assess the sensitivity of SH to changes in skin and subcutaneous tissue mechanical behaviour and thickness. For this purpose, the initial shear modulus of the skin or subcutaneous tissue was separately changed in the FE model and the respective change in SH was estimated. Literature on the inverse engineering of the heel pad's Ogden (1st order) hyperelastic coefficients presented standard deviations from the mean of up to ≈50% [20]. Based on that, it was decided to include two levels of tissue softening and stiffening in this analysis by reducing or increasing respectively the values of hyperelasticity coefficients by 25% and 50% relative to the reference values. Furthermore, to understand the effect of the non-linear nature of the tissue's mechanical behaviour, tissue softening or stiffening of 25% and 50% was first simulated by keeping the value of α constant and increasing or decreasing μ by 25% and 50%, respectively. The same change in the initial shear modulus was then also simulated by keeping μ constant and increasing or decreasing α by 25% and 50%, respectively (Eq. (3)). Seventeen scenarios were investigated in total for the effect of tissue stiffness (Table 1).

Three more scenarios were included in this analysis to test whether the effect of tissue thickness reported in the literature for a generalised indentation test [13] is also confirmed for SH. More specifically skin thinning, or thickening was simulated by reducing or increasing skin thickness by 25% relative to the reference value of 1.32 mm. These changes were decided based on the range of values of skin thickness reported in the literature [11]. To enable a direct comparison between the skin and subcutaneous tissue, subcutaneous tissue thickness was also reduced by 25% in a final simulation scenario. This was achieved by expanding the volume of the rigid calcaneus. Simulation of subcutaneous tissue thickening was not permitted by the FE model used in this analysis.

Table 1
The 17 tested scenarios on the effect of altered material properties on SH. For each scenario material coefficients for skin (μ_{skin}, α_{skin}) and subcutaneous soft tissue (μ_{sub}, α_{sub}) are defined either as reference values (Ref.) or as a percentage of change relative to reference (+50%,+25%,-25%,-50%). The respective change in initial shear modulus (G_0) and the calculated SH values are also shown.

Scenario	Material coefficients				G_0		SH
	μ_{skin}	α_{skin}	$\mu_{sub.}$	$\alpha_{sub.}$	Skin	Sub.	
1	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*	*Ref.*	**56**
2	**+50%**	*Ref.*	*Ref.*	*Ref.*	**+50%**	*Ref.*	**60**
3	**+25%**	*Ref.*	*Ref.*	*Ref.*	**+25%**	*Ref.*	**58**
4	**-25%**	*Ref.*	*Ref.*	*Ref.*	**-25%**	*Ref.*	**53**
5	**-50%**	*Ref.*	*Ref.*	*Ref.*	**-50%**	*Ref.*	**50**
6	*Ref.*	**+50%**	*Ref.*	*Ref.*	**+50%**	*Ref.*	**66**
7	*Ref.*	**+25%**	*Ref.*	*Ref.*	**+25%**	*Ref.*	**61**
8	*Ref.*	**-25%**	*Ref.*	*Ref.*	**-25%**	*Ref.*	**50**
9	*Ref.*	**-50%**	*Ref.*	*Ref.*	**-50%**	*Ref.*	**42**
10	*Ref.*	*Ref.*	**+50%**	*Ref.*	*Ref.*	**+50%**	**62**
11	*Ref.*	*Ref.*	**+25%**	*Ref.*	*Ref.*	**+25%**	**59**
12	*Ref.*	*Ref.*	**-25%**	*Ref.*	*Ref.*	**-25%**	**52**
13	*Ref.*	*Ref.*	**-50%**	*Ref.*	*Ref.*	**-50%**	**46**
14	*Ref.*	*Ref.*	*Ref.*	**+50%**	*Ref.*	**+50%**	**62**
15	*Ref.*	*Ref.*	*Ref.*	**+25%**	*Ref.*	**+25%**	**59**
16	*Ref.*	*Ref.*	*Ref.*	**-25%**	*Ref.*	**-25%**	**52**
17	*Ref.*	*Ref.*	*Ref.*	**-50%**	*Ref.*	**-50%**	**46**

3. Results

The predicted SH for the reference condition was equal to 56 and it changed linearly with the value of the material coefficients (Fig. 4). Changing either of the two material coefficients of subcutaneous tissue (i.e. $\mu_{sub.}$ or $\alpha_{sub.}$) had the same effect on SH. In this case, hardness appears to be sensitive only to changes in the tissue's initial stiffness. On the contrary, when the properties of skin were changed, SH was more sensitive to changes in α_{skin} than to changes in μ_{skin}. Indicatively, when α_{skin} was changed to reduce or increase skin initial stiffness by 25% (i.e. ±10.1 MPa change in initial shear modulus), then SH was reduced or increased by 11% or 9%, respectively. At the same time, a 25% reduction/ increase in the initial stiffness of the subcutaneous tissue (i.e. ±4.1

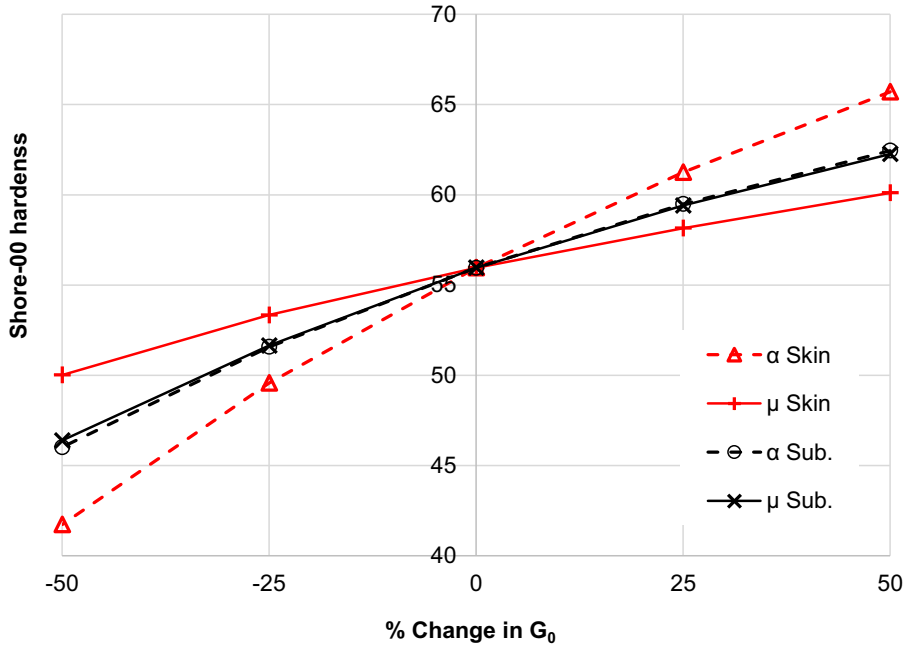

Fig. 4. The relationship between the numerically calculated Shore-00 hardness and changes in the initial shear modulus (G_0) of subcutaneous tissue (in black) and skin (in red). Different data series correspond to the cases where G_0 is changed by changing the value of μ (solid lines) or α (dotted lines). Percentage change in tissues stiffness is presented relative to the reference condition. The numeric values shown in this figure can be found in supplementary material.

MPa change in initial shear modulus) led to an 8% decrease or 6% increase in hardness respectively, irrespective of the material coefficient that was changed. Overall, it appears that SH is sensitive to changes in skin stiffness as well as to changes in subcutaneous tissue stiffness. Detailed results on the effect of altered material properties on SH can be found in Table 1.

With regards to the effect of tissue thickness, it was found that 25% thinning or thickening of skin (i.e. ±0.3 mm thickness change) led to 7% reduction or 6% increase in hardness respectively. At the same time, 25% reduction in the thickness of subcutaneous tissue (i.e. ±5.9 mm thickness change) led only to 2% increase in the estimated SH. These results confirm that SH is indeed significantly more sensitive to changes in skin thickness relative to changes in the thickness of the subcutaneous tissue.

4. Discussion

SH has been commonly used in literature to assess *in vivo* skin biomechanics [2–6,9,11]. However, this use is based on the hypothesis that the effect of subcutaneous tissue on the measurement is not significant. This hypothesis was not verified by the results of this study.

Even though previous research offers some indirect evidence that SH might be more relevant to skin biomechanics, these assertions are mainly based on the effect of tissue thickness [9,13]. The present study also confirms that SH is significantly more sensitive to changes in skin thickness than to changes in subcutaneous tissue thickness as indicated in literature [13]. However, the effect of tissue stiffness on SH had not been examined before.

In the present study, we assumed that if measurements of SH could indeed be interpreted as an assessment of skin biomechanics, then (similar to thickness) SH should also be significantly more sensitive to changes in skin stiffness than to changes in subcutaneous tissue stiffness. However, the present FE analysis indicates that this is not the case.

The results presented here show that SH can be as sensitive to changes in subcutaneous tissue stiffness as it is sensitive to changes in skin stiffness. Based on that, it is concluded that in layered structures, such as plantar soft tissue, SH is more representative of the macroscopic capacity of the bulk tissue to deform (i.e. bulk tissue deformability) rather than the stiffness of skin or any other individual constituent layer.

Moreover, the strong effect of skin thickness [13] means that a change over time or a between-populations difference in SH could be directly interpreted as change or difference in bulk tissue stiffness only if tissue thickness has remained the same. This highlights the need to complement SH measurements with measurements of skin thickness to assist the interpretation of results [5,8,9,11].

A difference between skin and subcutaneous tissue was found on the effect of their non-linear stress-strain behaviour. In the case of subcutaneous tissue, SH was sensitive only to changes in the tissue's initial stiffness (i.e., stiffness for small strains) and not to its strain softening/ hardening behaviour. On the contrary, the strain softening/ hardening behaviour of the skin had a significant effect on SH. This difference can be explained by the fact that strains in the subcutaneous tissue are significantly lower compared to the strains developed in the skin during SH testing.

In the present study the physical meaning of SH measurements was explored using an FE model of the heel. Despite the focus of the analysis on the plantar soft tissue, the findings and conclusions presented here are transferable to applications of SH in other anatomical areas that have a similar layered structure and mechanical properties.

The plantar soft tissue is among the key areas of application for *in vivo* measurements of tissue biomechanics using SH [5–10] as well as of more sophisticated indentation-based [16,21] or elastography-based methods [22,23]. This is because of the importance of plantar soft tissue mechanics, not only in understanding injury but for better clinical management of the foot at risk, such as diabetic foot complications [12].

Diabetes can affect the internal structure and mechanical characteristics of plantar soft tissues leading to increased stiffness and hardness [6,24–26]. In a seminal study in this area Piaggesi et al. [6] reported average(±STDEV) Shore-00 hardness values of 51.18(±6.19) and 43.18 (±3.26) for the heel pads of people with diabetes and their non-diabetic counterparts respectively. These measurements are within the range of SH values tested here (Table 1) which highlights the relevance of findings for healthy and diabetic populations.

With regards to the limitations of this FE analysis, skin and

subcutaneous tissue were simulated as individual layers of homogeneous, isotropic, hyperelastic materials. In reality, the subcutaneous tissue of the heel consists of two distinct layers of visco-hyperelastic tissues: the first being the microchamber layer, which is a thin layer of small septa comprised of elastin fibres, and the second, the macrochamber layer, which is a thick layer of larger septa comprised of roughly equal amounts of elastin fibres and collagen [27–30]. These two layers have been shown to exhibit different mechanical behaviour [31] and have different functional roles [32]. Simulating the anisotropic visco-hyperelastic mechanical behaviour of skin, microchamber and macrochamber layers could expand on the association between the measurement of SH and the mechanical properties of the skin and different subcutaneous layers. However, the key conclusion that SH cannot be considered as a direct measurement of skin properties, but as an assessment of bulk deformability is highly unlikely to have been altered by the inclusion of more layers with more complex mechanical behaviour or by the use of clinicaly relevant softer or stiffer tissue properties as reference.

The use of reference material properties from literature means that results should be interpreted as changes relative to the reference condition. Individual FE estimations of SH have limited clinical value on their own. It must be stressed that the purpose of the FE analysis presented here was solely to estimate the relative sensitivity of SH to altered tissue stiffness (skin or subcutaneous tissue). Subject-specific FE models of the *in vivo* SH test with subject-specific material properties will be needed to predict the absolute SH values.

5. Conclusions

SH is significantly affected by the stiffness and thickness of skin as well as by the stiffness of subcutaneous tissues. As a result, SH is unlikely to be a reliable measurement of skin biomechanics but an assessment of the macroscopic capacity to deform (deformability) of the bulk tissue (i.e., skin and subcutaneous tissue combined). Since increased or reduced deformability could be the result of changes in tissue stiffness and/or thickness, measurements of skin thickness are required to draw any conclusion with regards to bulk tissue stiffening or softening.

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Ethical approval

Not required

Declaration of Competing Interest

None declared

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2022.103816.

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