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

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Method Article

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

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Abstract:

Shore hardness (SH) is a non-invasive, cost-effective measurement of a tissue's resistance to indentation that can enhance clinical research and practice in areas like skin pathologies or diabetic foot ulceration. Even though the measurement itself is relatively simple, correctly interpreting its outcome is challenging. To support the effective use of SH 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. Twenty scenarios of altered tissue stiffness or thickness relative to the reference condition were investigated. 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 (0.3mm thickness change) or in subcutaneous tissue thickness (5.9mm thickness change) reduced SH by 7% or increased SH by 2% respectively. At the same time 25% reduction in the initial stiffness of skin (10.1MPa stiffness change) or of subcutaneous tissue (4.1MPa stiffness change) 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.

Keywords: plantar soft tissue, skin, subcutaneous tissue, stiffness, hardness, finite element, in vivo testing

1. Introduction

Shore hardness (SH) is a measurement of a material's resistance to indentation. 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.

To measure SH *in vivo*, a specialised durometer (Figure 1a) is pressed against the skin surface by the full weight of the device before taking the hardness reading (Figure 1b). The instrument has an internal spring mechanism which pushes a small indenter causing an ident into 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[1–3] and to study *in vivo* the biomechanics of the soft tissues of the sole of the foot (plantar soft tissue)[4–10]. 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[11]. 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 [1–5,8,10] there is also a small number of studies where SH is reported as a measurement of bulk tissue biomechanics[6,7,9] (i.e. skin and subcutaneous tissue). Identifying the correct interpretation of SH depends on the effect of subcutaneous tissues on the measurement and whether this can be considered negligible. Previous research has demonstrated that indentation tests that use small indenters (such as SH) are affected significantly more strongly by the thickness of skin relative to the thickness of the subcutaneous tissue[12]. Based on this finding it is reasonable to suspect that SH is more relevant to skin rather than subcutaneous or bulk tissue biomechanics[12]. 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 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

Considering the importance of tissue biomechanics for the study and clinical management of diabetic foot complications, this FE analysis was focused on the plantar soft tissue. To this end, a 3D model of a Shore-00 durometer was created and validated before being used to simulate SH testing at the heel. 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: 2.4mm), a rigid disk (diameter: 18mm) 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 (Figure 2a). During the measurement of hardness, the rigid disk is pressed against the surface of the tested material with a net force equal to the durometer's weight (1.96N). 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 (Figure 2b). The initial distance between the indenter's tip and the surface of the rigid disk (d_s) is 2.4mm, and the magnitude of the force on the tip increases linearly from the pretension value of 0.23N (for d_s= 2.4mm) to a maximum value of 1.1N 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= 2.4mm) to a maximum value of a hundred (for d_s=0).

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

The accuracy of the durometer model was tested for a polyurethane (PU) foam with known mechanical properties (μ_{PU} =39.6 kPa, α_{PU}=19.3, v_{PU}= 0.06, Eq.4)[13] which is used in therapeutic footwear. To this end, Shore-00 hardness was measured on twelve sites on a 10mm thick material sheet (width= length= 150mm). The FE model of the Shore-00 durometer was then used to simulate the hardness test (Figure 2c) enabling the direct comparison between experimentally measured and numerically estimated Shore-00 hardness.

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

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

where $\bar{\lambda}_p^{\,a_{foam}}(p = 1,2,3)$ 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 (v).

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[14] was modified to include a layer of skin (thickness=1.32mm)[10] and to simulate the hardness test (Figure 3). 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[14]. 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 analysis. In the final model, the thickness of the subcutaneous tissue along the axis of the SH durometer was equal to 23.65mm.

Due to the nature of the applied loading only a cylindrical section of the heel model was meshed (Figure 2). This cylindrical section was directly over the apex of the calcaneus, and its diameter was significantly wider than the durometer (67% wider than the base of the durometer). Preliminary analysis indicated that the results of the simulation were not affected by this simplification. The final FE model comprised 83,888 tetrahedral four-node elements. Element size was decided through a sensitivity analysis to eliminate any mesh dependency phenomena.

The mechanical behaviour of the subcutaneous tissue and skin was simulated using the 1st order Ogden hyperelastic material model[14–17]:

$$W = \frac{\mu}{\alpha}(\lambda_1^{-\alpha} + \lambda_2^{-\alpha} + \lambda_3^{-\alpha} - 3) + \frac{1}{d_k}(J-1)^2, \quad \text{Eq.2}$$

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

where λ_1, λ_2, λ_3 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). Initial shear modulus offers an indirect assessment of the material's stiffness for small strains. Parameter d_k is a function of both the effective Poisson's ratio (v) and the initial shear modulus (G_0):

$$d_k = \frac{3(1-2\nu)}{G_0(\nu+1)} \quad \text{Eq.6}$$

Reference values of μ and α were adopted from the literature for skin (μ_{skin}=3.57kPa, α_{skin}=22.71)[16] and subcutaneous tissue (μ_{sub}=4.82kPa, α_{sub}=6.82)[17]. Both tissues were assumed to be nearly incompressible (v=0.475)[15].

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 (1^{st} order) hyperelastic coefficients presented standard deviations from the mean of up to ≈50%[17]. Based on that, it was decided to include two levers of tissue softening/stiffening in this analysis by reducing/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.

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[12] 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 1.32mm. These changes were decided based on the range of values of skin thickness reported in the literature[10]. 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.

3. Results

The predicted SH for the reference condition was equal to 56 and it changed linearly with the value of the material coefficients (Figure 4). Changing either of the two material coefficients of subcutaneous tissue (i.e. μ_{sub} or α_{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 then 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. ±10.1MPa initial stiffness change), then SH decreased or increased by 11% or 9% respectively. The same time, a 25% increase/reduction in the initial stiffness of the subcutaneous tissue (i.e. ±4.1MPa initial stiffness change) 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.

With regards to the effect of tissue thickness, it was found that 25% thinning or thickening of skin (i.e. ±0.3mm thickness change) led to 7% reduction or 6% increase in hardness. At the same time, 25% reduction in the thickness of subcutaneous tissue (i.e. ±5.9mm 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.

A detailed table of the calculated SH for all simulated scenarios can be found in the Supplementary material.

4. Discussion

SH has been commonly used in literature to assess *in vivo* skin biomechanics[1–5,8,10]. 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[8,12]. The present study also confirms that SH is significantly more sensitive to changes in skin thickness than to changes in subcutaneous tissue thickness. 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. 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[12] 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[4,7,8,10].

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 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.

The plantar soft tissue is among the key areas of application for *in vivo* measurements of tissue biomechanics using SH[4–9] as well as of more sophisticated indentation-based[14,18] or elastography-based methods[19,20]. This is because of the

267 importance of plantar soft tissue mechanics in the mechanisms for injury and the
268 prevention/management of foot related pathologies, such as diabetic foot ulceration[11].

269 With regards to the FE model design, skin and subcutaneous tissue are simulated
270 as individual layers of homogeneous, isotropic, hyperelastic materials. In reality, the
271 subcutaneous tissue of the heel consists of two distinct layers of visco-hyperelastic
272 tissues: the first being the microchamber layer, which is a thin layer of small septa
273 comprised of elastin fibres, and the second, the macrochamber layer, which is a thick
274 layer of larger septa comprised of roughly equal amounts of elastin fibres and
275 collagen[21–24]. These two layers have been shown to exhibit different mechanical
276 behaviour[25] and have different functional roles[26]. Simulating the anisotropic visco-
277 hyperelastic mechanical behaviour of skin, microchamber and macrochamber layers
278 could expand on the association between the measurement of SH and the mechanical
279 properties of the skin and different subcutaneous layers. However, the key conclusion
280 that SH cannot be considered as a direct measurement of skin properties, but as an
281 assessment of bulk deformability is highly unlikely to have been altered by the inclusion
282 of more layers with more complex mechanical behaviour. It must also be stressed that
283 the purpose of the FE analysis presented here was solely to estimate the relative
284 sensitivity of SH to altered tissue stiffness (skin or subcutaneous tissue). Subject-specific
285 FE models of the *in vivo* SH test with subject specific material properties will be needed
286 to predict the absolute SH values.

287

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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 (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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Figures:

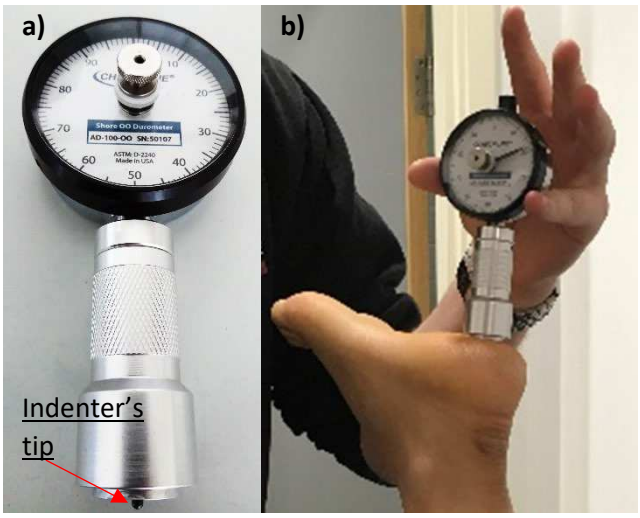
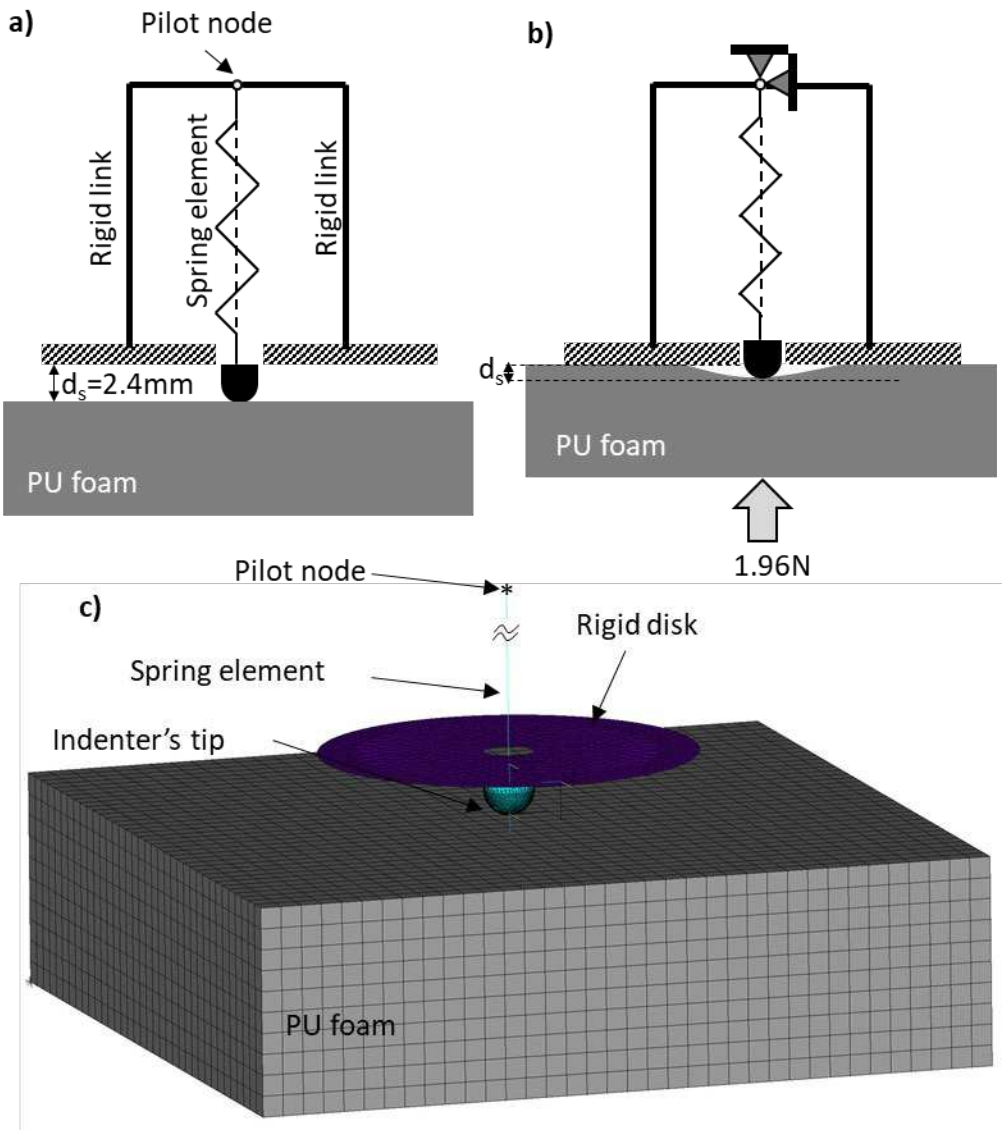


Figure 1: A Shore-00 durometer (a) and the testing set-up for the measurement of SH at the heel (b).



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

426

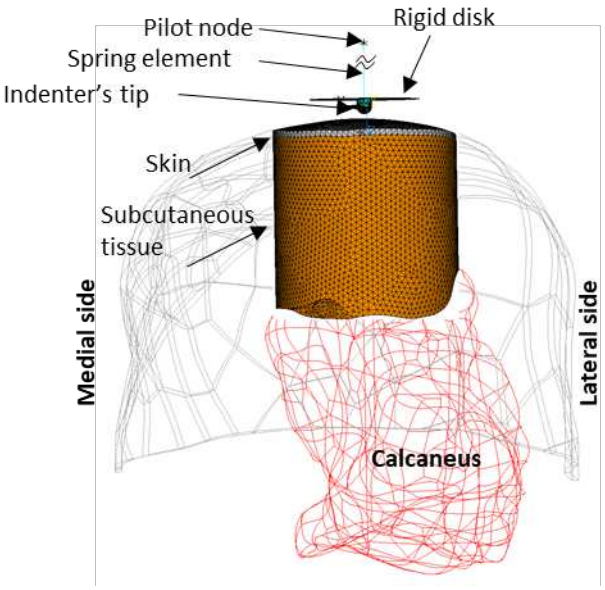
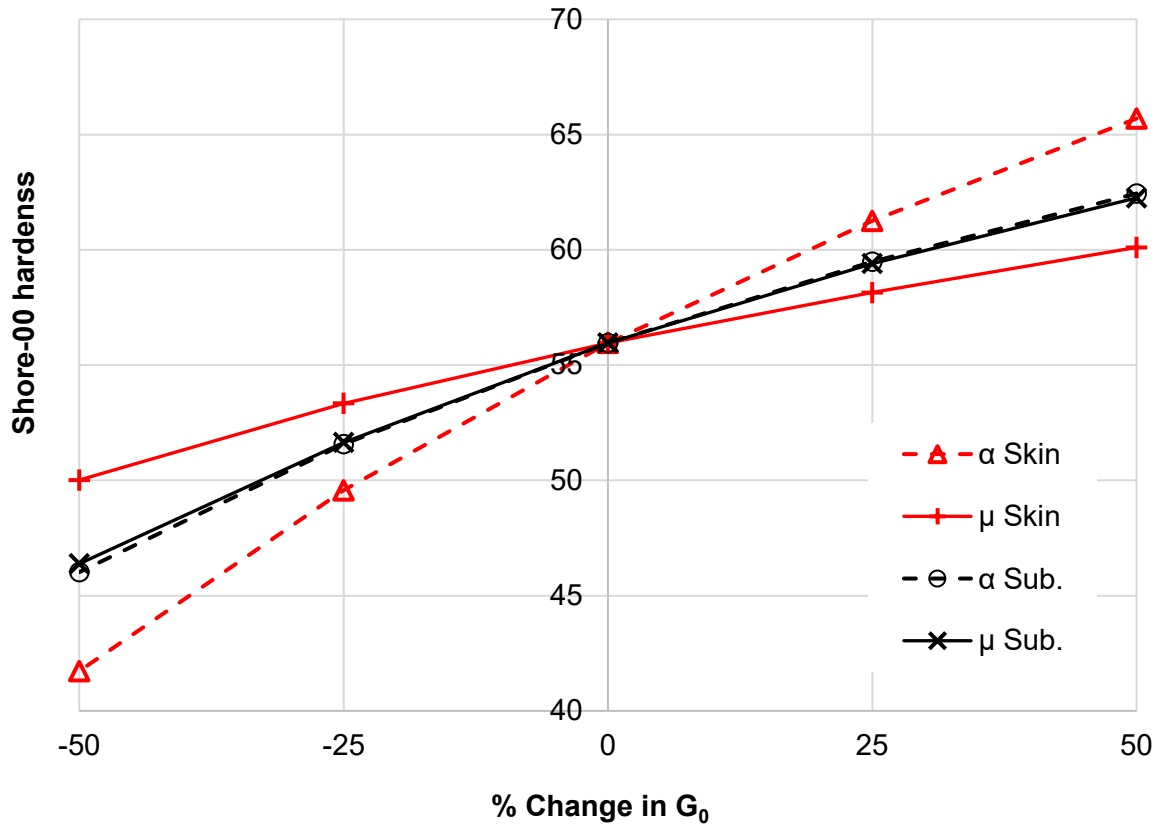


Figure 3: Frontal view of the meshed model of the SH test at the heel. An outline of the entire heel geometry is also shown for reference.



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448 **Figure 4:** The relationship between the numerically calculated Shore-00 hardness and
449 changes in the initial shear stiffness (G_0) of subcutaneous tissue (in black) and skin (in
450 red). Percentage changes in tissues stiffness are presented relative to the reference
451 condition.

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Supplementary Files

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